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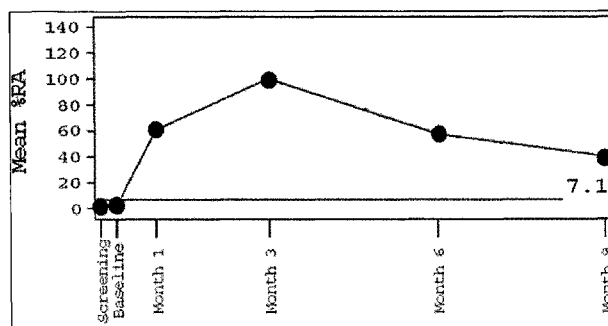


Figure 1

(57) Abstract: The present invention provides methods of inducing anti-glatiramer acetate specific antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA specific antibodies in the blood or serum of the human subject i) increases for up to about 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject.

METHOD OF INDUCING ANTI-GLATIRAMER ACETATE ANTIBODY RESPONSE

This application claims the priority of U.S. Serial No. 14,800,014, filed July 15, 2015 and U.S. Provisional Application No. 62/109,033, filed January 28, 2015, the contents of each of which are hereby
5 incorporated by reference.

Throughout this application, various publications are referenced, including referenced by Arabic numerals. Full citations for publications referenced in Arabic numerals may be found listed at the end of the specification immediately preceding the claims. The
10 disclosures of all referenced publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

BACKGROUND OF THE INVENTION

15 Multiple sclerosis (MS) is a chronic, debilitating autoimmune disease of the central nervous system (CNS) with either relapsing-remitting (RR) or progressive course leading to neurologic deterioration and disability. At time of initial diagnosis, RRMS is the most common form of the disease (1) which is characterized by unpredictable acute
20 episodes of neurological dysfunction (relapses), followed by variable recovery and periods of clinical stability. The vast majority of RRMS patients eventually develop secondary progressive (SP) disease with or without superimposed relapses. Around 15% of patients develop a sustained deterioration of their neurological function from the
25 beginning; this form is called primary progressive (PP) MS. Patients who have experienced a single clinical event (Clinically Isolated Syndrome or "CIS") and who show lesion dissemination on subsequent magnetic resonance imaging (MRI) scans according to McDonald's criteria, are also considered as having relapsing MS (2).

30 With a prevalence that varies considerably around the world, MS is the most common cause of chronic neurological disability in young adults (3, 4). Anderson et al. estimated that there were about 350,000 physician-diagnosed patients with MS in the United States in 1990

(approx. 140 per 100,000 population) (5). It is estimated that about 2.5 million individuals are affected worldwide (6). In general, there has been a trend toward an increasing prevalence and incidence of MS worldwide, but the reasons for this trend are not fully understood (5).

Current therapeutic approaches consist of i) symptomatic treatment ii) treatment of acute relapses with corticosteroids and iii) treatment aimed to modify the course of the disease. Currently approved therapies target the inflammatory processes of the disease. Most of them are considered to act as immunomodulators but their mechanisms of action have not been completely elucidated. Immunosuppressants or cytotoxic agents are also used in some patients after failure of conventional therapies. Several medications have been approved and clinically ascertained as efficacious for the treatment of RR-MS; including BETASERON®, AVONEX® and REBIF®, which are derivatives of the cytokine interferon beta (IFNB), whose mechanism of action in MS is generally attributed to its immunomodulatory effects, antagonizing pro-inflammatory reactions and inducing suppressor cells. Other approved drugs for the treatment of MS include Mitoxantrone and Natalizumab (7).

Copaxone® (Teva Pharmaceutical Industries Ltd.) is indicated for the treatment of patients with relapsing forms of multiple sclerosis. Copaxone® is a clear, colorless to slightly yellow, sterile, nonpyrogenic solution for subcutaneous injection (8). Each 1 mL of Copaxone® solution contains 20mg or 40mg of the active ingredient, glatiramer acetate (GA), the inactive ingredient, 40mg of mannitol(8).

GA, the active ingredient of Copaxone®, consists of the acetate salts of synthetic polypeptides, containing four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine with an average molar fraction of 0.141, 0.427, 0.095, and 0.338, respectively. Glatiramer acetate is identified by specific antibodies (8).

GA elicits anti-inflammatory as well as neuroprotective effects in various animal models of chronic inflammatory and neurodegenerative diseases (9-13) and has been shown to be safe and effective in reducing

relapses and delaying neurologic disability in MS patients following long-term treatment (14).

The mechanisms underlying GA therapeutic activity are not fully elucidated, but GA activity on immune cells has been well demonstrated. GA appears to act as an altered peptide ligand (APL) of encephalitogenic epitopes within myelin basic protein (MBP) (15) and demonstrates cross-reactivity with MBP at the humoral and cellular levels (16-22). The unique antigenic sequences of the GA polypeptide mixture compete with myelin antigens for binding to MHC class II molecules on antigen presenting cells (APCs) and presentation to the T cell receptor (TCR), resulting in the induction of anergy or deletion of autoreactive MBP-reactive T cells and proliferation of GA-reactive T cells. At initiation of Copaxone® treatment, GA-reactive CD4+ T-cell lines from MS patients secrete both pro-inflammatory T helper type 1 (Th1) and anti-inflammatory Th2 cytokines (20, 23), but continued exposure to Copaxone® induces a shift in GA-reactive T cells toward the Th2 phenotype (20, 22, 24-27). In MS patients treated with daily subcutaneous Copaxone 20 mg/ml, anti-GA antibody peaked at 3 months after initiation of treatment, decreasing at 6 months and remaining low, and IgG1 antibody levels were 2-3 fold higher than those of IgG2 (28).

Copaxone® also increases the number and suppressive capacity of CD4+CD25+FOXP3+ regulatory T cells, which are functionally impaired in MS patients (29-31). Furthermore, treatment leads to antigen-nonspecific modulation of APC function. Copaxone® treatment promotes development of anti-inflammatory type II monocytes characterized by an increase in interleukin (IL)-10 and transforming growth factor-beta (TGF-β) and decreased production of IL-12 and tumor necrosis factor (TNF) (32).

SUMMARY OF THE INVENTION

The present invention provides a method of inducing anti-glatiramer acetate (GA) specific antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA specific antibodies in the blood or serum of the human subject

- i) increases for up to about 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject;
- ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
- iii) peaks at about 3 or about 6 months or between about 3 and about 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
- iv) is higher than baseline at least about 12 months after the initial 40 mg/ml dose of glatiramer acetate.

The present invention provides a method of producing a glatiramer acetate response profile for a human subject afflicted with multiple sclerosis comprising the steps of:

- a) obtaining blood or serum samples periodically collected from a human subject afflicted with multiple sclerosis who is administered three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least about 12 or at least about 24 months after the initial 40 mg/ml dose of glatiramer acetate is administered;
- b) assaying whether the level of anti-glatiramer acetate (GA) specific antibodies in the blood or serum of the human subject
 - i) increases for up to about 6 months after the initial

- 40 mg/ml dose of glatiramer acetate;
 - ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
 - iii) peaks at about 3 or about 6 months or between about 3 and about 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
 - iv) is higher than baseline about 12 and about 24 months after the initial 40 mg/ml dose of glatiramer acetate,
- c) producing the glatiramer acetate response profile of the human subject comprising the level of anti-GA specific antibodies determined in step b).

The present invention provides a method of inducing anti-glatiramer acetate (GA) specific antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA specific antibodies in the blood or serum of the human subject

- i) increases for up to 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject;
- ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
- iii) peaks at 3 or 6 months or between 3 and 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
- iv) is higher than baseline at least 12 months after the initial 40 mg/ml dose of glatiramer acetate,

wherein the 40 mg/ml dose of glatiramer acetate is in a prefilled syringe containing 1ml of an aqueous pharmaceutical solution

of 40mg/ml of glatiramer acetate and 40mg/ml mannitol, and wherein the aqueous pharmaceutical solution

a) has a viscosity in the range of 2.0-3.5 cPa; or

b) has an osmolality in the range of 270-330 mosmol/Kg.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Anti-GA specific antibody response profile in patients who were treated with Copaxone® 20 mg/ml subcutaneously daily for 9 months. Anti-GA specific antibodies were detected using enzyme-linked immunosorbant assay (ELISA). The line representing cut-point value crosses the Y axis at 7.1(RA%).

Figure 2. Anti-GA specific antibody response in patients who were treated with Copaxone® 20mg/ml subcutaneously daily for 2 years. Anti-GA specific antibodies were detected using either (A) radioimmunoassay (RIA), and (B) ELISA techniques.

Figure 3. Anti-GA specific antibody response in patients who were treated with Copaxone® 40mg/ml subcutaneously three times per week for 2 years. The line representing cut-point value crosses the Y axis at 1.4(RA%).

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a method of inducing anti-glatiramer acetate (GA) specific antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA specific antibodies in the blood or serum of the human subject

- i) increases for up to about 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject;
- ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
- iii) peaks at about 3 or about 6 months or between about 3 and about 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
- iv) is higher than baseline at least about 12 months after the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases for about 3 to about 6 months after the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week are administered to the human subject for at least 18 months, and the level of anti-GA specific antibodies in the blood or serum of the human subject is higher than baseline about 18 months after the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week are administered to the human subject for at least 24 months, and the level of anti-GA specific antibodies in the blood or serum of the human subject is higher than baseline about 24 months after the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, the anti-GA specific antibodies are other than IgM or IgE antibodies.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases

- i) to at least about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 67.5, about 70, about 75, about 80, about 25 to about 50, about 29 to about 106, about 29 to about 60, about 31 to about 60, about 35 to about 70, about 39 to about 71, about 50 to about 75, about 75 to about 80, or about 50 to about 80 RA% within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by an enzyme-linked immunosorbent assay (ELISA);
- ii) by at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150, about 25.9 to about 975, or about 100 to about 200-fold increase in RA% over baseline within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA; or
- iii) to at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150 or about 100 to about 200-fold over baseline.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 34, about 35, or about 35 to about 70 RA% within about 1 month after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 67.5

or about 29 to about 106 RA% within about 3 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 40 or about 39 to about 71 RA% within about 6 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 30 or about 31 to about 60 RA% within about 9 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 30 or about 30 to about 60 RA% within about 12 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 25 or about 25 to about 50 RA% within about 18 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 25 or about 25 to about 50 RA% within about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

The present invention provides a method of producing a glatiramer acetate response profile for a human subject afflicted with multiple sclerosis comprising the steps of:

- a) obtaining blood or serum samples periodically collected from a human subject afflicted with multiple sclerosis who is administered three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least about 12 or at least about 24 months after the initial 40 mg/ml dose of glatiramer acetate is administered;

- b) assaying whether the level of anti-glatiramer acetate (GA) specific antibodies in the blood or serum of the human subject
 - i) increases for up to about 6 months after the initial 40 mg/ml dose of glatiramer acetate;
 - ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
 - iii) peaks at about 3 or about 6 months or between about 3 and about 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
 - iv) is higher than baseline about 12 and about 24 months after the initial 40 mg/ml dose of glatiramer acetate,
- c) producing the glatiramer acetate response profile of the human subject comprising the level of anti-GA specific antibodies determined in step b).

In some embodiments, the method comprises assaying whether the level of anti-GA specific antibodies in the blood or serum of the human subject increases for about 3 to about 6 months after the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, the method further comprises assaying whether the anti-GA specific antibodies are other than IgM or IgE antibodies, and the glatiramer acetate response profile of the human subject produced in step c) identifies the anti-GA specific antibodies as other than IgM or IgG antibodies.

In some embodiments, the glatiramer acetate response profile is a written glatiramer acetate response profile report.

In some embodiments, step b) comprises assaying whether the level of anti-GA specific antibodies in the blood or serum of the human subject increases

- i) to at least about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 67.5, about 70, about 75, about 80, about 25 to about 50, about 29 to about 106, about 29 to about 60, about 31 to about 60, about 35 to about 70, about 39 to about 71, about 50 to about 75, about 75 to about 80, or about 50 to about 80 RA% within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by an enzyme-linked immunosorbent assay (ELISA);
- ii) by at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150, about 25.9 to about 975, or about 100 to about 200-fold increase in RA% over baseline within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA; or
- iii) to at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150 or about 100 to about 200-fold over baseline.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 34, about 35, or about 35 to about 70 RA% within about 1 month after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 67.5 or about 29 to about 106 RA% within about 3 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 40 or

about 39 to about 71 RA% within about 6 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 30 or about 31 to about 60 RA% within about 9 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 30 or about 30 to about 60 RA% within about 12 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 25 or about 25 to about 50 RA% within about 18 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the level of anti-GA specific antibodies in the blood or serum of the human subject increases to at least about 25 or about 25 to about 50 RA% within about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA.

In some embodiments, the three subcutaneous injections are on three days each week selected from the group consisting of day 1, day 3 and day 5; day 1, day 3 and day 6; day 1, day 4 and day 6; day 2, day 4 and day 6; day 2, day 4 and day 7; 2, day 5 and day 7; and day 3, day 5 and day 7.

In some embodiments, the glatiramer acetate is present in 1ml of a pharmaceutical composition in a prefilled syringe for self-administration by the human subject.

In some embodiments, the pharmaceutical composition further comprises mannitol and has a pH in the range of 5.5 to 7.0.

In some embodiments, the 40 mg/ml dose of glatiramer acetate is in a prefilled syringe containing 40mg of glatiramer acetate and 40mg mannitol.

In some embodiments, the prefilled syringe contains 1ml of an aqueous pharmaceutical solution of 40mg/ml of glatiramer acetate and 40mg/ml mannitol.

In some embodiments, the aqueous pharmaceutical solution

- 5 a) has a viscosity in the range of 2.0-3.5 cPa; or
- b) has an osmolality in the range of 270-330 mosmol/Kg.

In some embodiments, the aqueous pharmaceutical solution

- a) has a viscosity in the range of 2.2-3.0 cPa; or
- b) has an osmolality in the range of 275-325 mosmol/Kg.

In some embodiments, the 40 mg/ml dose of glatiramer acetate is an aqueous pharmaceutical solution comprising 40mg/ml glatiramer acetate and 40mg/ml mannitol, wherein the aqueous pharmaceutical solution

- a) has a viscosity in the range of 2.0-3.5 cPa; or
- b) has an osmolality in the range of 275-325 mosmol/Kg.

In some embodiments, the aqueous pharmaceutical solution has a viscosity in the range of 2.0-3.5 cPa.

In some embodiments, the aqueous pharmaceutical solution has a viscosity in the range of 2.61-2.92 cPa.

In some embodiments, the aqueous pharmaceutical solution has an osmolality in the range of 275-325 mosmol/Kg.

In some embodiments, the aqueous pharmaceutical solution has an osmolality in the range of 300-303 mosmol/Kg.

In some embodiments, the human subject is suffering from relapsing-remitting multiple sclerosis (RRMS).

In some embodiments, the human subject is suffering from multiple sclerosis other than RRMS.

In some embodiments, the human subject is suffering from progressive-relapsing multiple sclerosis, secondary progressive multiple sclerosis, or primary progressive multiple sclerosis.

In some embodiments, the human subject has previously received administration of a 20 mg/ml dose of glatiramer acetate.

In some embodiments, the human subject is a naïve subject or has been previously administered a multiple sclerosis drug other than glatiramer acetate.

In some embodiments, the multiple sclerosis drug other than glatiramer acetate is interferon β -1a, interferon β -1b, mitoxantrone, natalizumab, fingolimod, teriflunomide, or dimethyl fumarate.

In some embodiments, the human subject has a genotype comprising:

one or more A alleles at the location of one or more single nucleotide polymorphisms (SNPs) selected from the group consisting of: kgp10152733, kgp10224254, kgp10305127, kgp10351364, kgp10372946, kgp10404633, kgp10564659, kgp10591989, kgp10594414, kgp10619195, kgp10620244, kgp10633631, kgp10974833, kgp11002881, kgp11285862, kgp11328629, kgp11407560, kgp11514107, kgp11627530, kgp11702474, kgp11711524, kgp11768533, kgp11804835, kgp12083934, kgp12182745, kgp12230354, kgp1224440, kgp124162, kgp12557319, kgp1371881, kgp1699628, kgp1753445, kgp1779254, kgp1786079, kgp18379774, kgp18525257, kgp20163979, kgp2023214, kgp20478926, kgp21171930, kgp2262166, kgp22778566, kgp2465184, kgp24753470, kgp25191871, kgp25216186, kgp25952891, kgp26026546, kgp26533576, kgp27500525, kgp27571222, kgp28532436, kgp28586329, kgp28817122, kgp2958113, kgp29794723, kgp30282494, kgp304921, kgp3205849, kgp3218351, kgp3276689, kgp337461, kgp345301, kgp355027, kgp355723, kgp3593828, kgp3812034, kgp3951463, kgp4162414, kgp4223880, kgp4418535, kgp4543470, kgp4573213, kgp4634875, kgp4755147, kgp4842590, kgp485316, kgp5068397, kgp5334779, kgp5483926, kgp5564995, kgp5869992, kgp5908616, kgp6032617, kgp6038357, kgp6076976, kgp6091119, kgp6127371, kgp61811, kgp6214351, kgp6228750,

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rs2824070, rs2845371, rs2857103, rs2926455, rs343087, rs343092,
rs3767955, rs3792135, rs3829539, rs3899755, rs4075692,
rs4143493, rs423239, rs4254166, rs4356336, rs4584668, rs4780822,
rs4782279, rs5024722, rs6032209, rs6110157, rs623011, rs6497396,
rs6845927, rs6895094, rs6899068, rs7024953, rs7028906,
rs7029123, rs7062312, rs7187976, rs7191155, rs720176, rs7228827,
rs7496451, rs7563131, rs759458, rs7666442, rs7670525, rs7677801,
rs7725112, rs7850, rs7862565, rs7948420, rs8035826, rs8053136,
rs8055485, rs823829, rs9315047, rs9501224, rs9508832, rs950928,
rs9597498, rs9670531, rs9671124, rs9817308, rs9834010, rs9876830
or rs9931211;

one or more C alleles at the location of one or more SNPs selected
from the group consisting of: kgp10910719, kgp11077373,
kgp11453406, kgp12426624, kgp2045074, kgp22811918, kgp23298674,
kgp2709692, kgp28687699, kgp3496814, kgp3669685, kgp3730395,
kgp4056892, kgp4370912, kgp5053636, kgp5216209, kgp5292386,
kgp6023196, kgp652534, kgp7059449, kgp7189498, kgp7521990,

kgp7792268, kgp8303520, kgp9320791, kgp9795732, rs10201643, rs11022778, rs11136970, rs11147439, rs11691553, rs1579771, rs16901784, rs2136408, rs2325911, rs241443, rs2857104, rs3803277, rs3885907, rs4738738, rs4894701, rs502530, rs6032205, rs6687976, rs6718758, rs6835202, rs714342, rs7524868, rs7844274, rs9393727 or rs9671182; or

one or more G alleles at the location of one or more SNPs selected from the group consisting of: kgp10090631, kgp1009249, kgp10412303, kgp10523170, kgp1054273, kgp10558725, kgp10632945, kgp10679353, kgp10788130, kgp10826273, kgp10922969, kgp10948564, kgp10967046, kgp1098237, kgp11010680, kgp11141512, kgp11206453, kgp11210903, kgp1124492, kgp11281589, kgp11356379, kgp11467007, kgp11543962, kgp11580695, kgp11633966, kgp11686146, kgp11843177, kgp12008955, kgp12371757, kgp1285441, kgp13161760, kgp1355977, kgp15390522, kgp1683448, kgp1688752, kgp1912531, kgp19568724, kgp2092817, kgp2245775, kgp22793211, kgp22823022, kgp2282938, kgp2299675, kgp2356388, kgp23672937, kgp23737989, kgp2388352, kgp2391411, kgp24131116, kgp24415534, kgp2446153, kgp2451249, kgp24729706, kgp25543811, kgp25921291, kgp26271158, kgp2638591, kgp26528455, kgp2688306, kgp26995430, kgp270001, kgp2715873, kgp27640141, kgp2788291, kgp2923815, kgp29367521, kgp293787, kgp2959751, kgp297178, kgp3048169, kgp3182607, kgp3202939, kgp3267884, kgp3418770, kgp3450875, kgp3477351, kgp3598409, kgp3651767, kgp3854180, kgp3933330, kgp3984567, kgp4011779, kgp4096263, kgp4127859, kgp4155998, kgp4346717, kgp4420791, kgp4479467, kgp4524468, kgp4559907, kgp4705854, kgp4734301, kgp4812831, kgp487328, kgp4898179, kgp5002011, kgp5014707, kgp5017029, kgp512180, kgp5144181, kgp5159037, kgp5388938, kgp5409955, kgp5440506, kgp5441587, kgp55646, kgp5579170, kgp5680955, kgp6190988, kgp6539666, kgp6567154, kgp6599438, kgp6603796, kgp6737096, kgp6768546, kgp6835138, kgp6996560, kgp7063887, kgp7092772, kgp7121374, kgp7181058, kgp7331172, kgp7416024, kgp7481870, kgp767200, kgp7714238, kgp7747883, kgp8107491, kgp8169636, kgp8174785, kgp8183049, kgp8192546, kgp8335515, kgp8437961, kgp8440036, kgp85534, kgp8599417, kgp8767692, kgp8777935, kgp8817856,

kgp8869954, kgp9071686, kgp9078300, kgp9354820, kgp9421884, kgp9551947, kgp9601362, kgp9627406, kgp9699754, kgp971582, kgp9854133, rs1079303, rs10841322, rs10954782, rs11002051, rs11029907, rs11083404, rs11085044, rs11192461, rs1157449, rs12494712, rs12943140, rs13002663, rs13419758, rs1380706, rs1387768, rs1410779, rs1508102, rs1532365, rs16886004, rs16895510, rs16927077, rs16930057, rs17224858, rs17238927, rs17329014, rs17638791, rs1886214, rs1894408, rs196295, rs196341, rs196343, rs1979992, rs1979993, rs2043136, rs2071470, rs2074037, rs2175121, rs241435, rs241447, rs241451, rs241452, rs241454, rs2598360, rs2621321, rs2621323, rs2816838, rs2839117, rs2857101, rs2934491, rs3135388, rs3218328, rs3799383, rs3815822, rs3818675, rs419132, rs4360791, rs4449139, rs4669694, rs4709792, rs4769060, rs4822644, rs484482, rs543122, rs6535882, rs6840089, rs7020402, rs7217872, rs7348267, rs7579987, rs7672014, rs7860748, rs7864679, rs7928078, rs8050872, rs858341, rs931570, rs9346979, rs9376361, rs9579566, rs9913349 or rs9931167, or one or more T alleles at the location of kgp18432055, kgp279772, kgp3991733 or kgp7242489.

The method of any one of claims 1-30, wherein assaying the level of anti-GA specific antibodies comprises an enzyme-linked immunosorbent assay (ELISA) or a radioimmunoassay.

The method of claim 31, wherein assaying the level of anti-GA specific antibodies comprises ELISA.

In some embodiments, the baseline level of anti-GA specific antibodies is

- i) the level of anti-GA specific antibodies in a corresponding naïve human subject afflicted with multiple sclerosis;
- ii) the level of anti-GA specific antibodies in a corresponding naïve healthy human subject;
- iii) the level of anti-GA specific antibodies in the human subject before the human subject has been administered the after the initial 40 mg/ml dose of glatiramer acetate; or

- iv) the level of anti-GA specific antibodies in the human subject concurrently with administration of the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, the baseline level of anti-GA specific antibodies is the RA% for

- i) the level of anti-GA specific antibodies in a corresponding naïve human subject afflicted with multiple sclerosis;
- ii) the level of anti-GA specific antibodies in a corresponding naïve healthy human subject;
- iii) the level of anti-GA specific antibodies in the human subject before the human subject has been administered the after the initial 40 mg/ml dose of glatiramer acetate; or
- iv) the level of anti-GA specific antibodies in the human subject concurrently with administration of the initial 40 mg/ml dose of glatiramer acetate.

In some embodiments, the ELISA is solid-phase ELISA.

The present invention provides a method of inducing anti-glatiramer acetate (GA) antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA antibodies in the blood or serum of the human subject

- i) increases for up to 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject;
- ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
- iii) peaks at 3 or 6 months or between 3 and 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
- iv) is higher than baseline at least 12 months after the initial 40 mg/ml dose of glatiramer acetate,

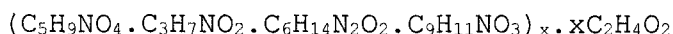
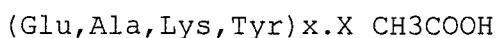
wherein the 40 mg/ml dose of glatiramer acetate is in a prefilled syringe containing 1ml of an aqueous pharmaceutical solution of 40mg/ml of glatiramer acetate and 40mg/ml mannitol, and wherein the aqueous pharmaceutical solution

- 5 a) has a viscosity in the range of 2.0-3.5 cPa; or
- b) has an osmolality in the range of 270-330 mosmol/Kg.

All combinations of the various elements described herein are within the scope of the invention.

Definitions

- 10 As used herein, "glatiramer acetate" is a complex mixture of the acetate salts of synthetic polypeptides, containing four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine. The peak average molecular weight of glatiramer acetate is between 5,000 and 9,000 daltons. Chemically, glatiramer acetate is
- 15 designated L-glutamic acid polymer with L-alanine, L-lysine and L-tyrosine, acetate (salt). Its structural formula is:



CAS-147245-92-9 (8).

- 20 "RA%" or "RA(%)" is calculated by the following equation:

$$\text{RA}(\%) = \frac{\text{AVG test sample ABS} - \text{AVG Blank ABS}}{\text{AVG SST ABS} - \text{AVG SST Blank ABS}} \times 100$$

where "AVG test sample ABS" means average absorbance (ABS) of each test sample and/or control;

- where "Blank" is one or more wells coated with GA without human serum
- 25 sample;

where "AVG Blank ABS" is average absorbance (ABS) of Blank;

where "SST" is System Suitability Test which is one or more wells coated with purified human IgG;

where "AVG SST ABS" is average absorbance (ABS) of the SST; and

where "SST Blank" is one or more wells coated with the blocking buffer only, with neither hIgG nor human serum sample.

Glatiramer acetate may be abbreviated herein as "GA."

As used herein, "anti-GA antibodies" and "anti-GA specific antibodies" are immunoglobulin (Ig) molecules which specifically recognize GA.

As used herein, the "administration" of glatiramer acetate may be oral, nasal, pulmonary, parenteral, intravenous, intra-articular, transdermal, intradermal, subcutaneous, topical, intramuscular, rectal, intrathecal, intraocular, buccal or by gavage.

10 As used herein, "Benign Multiple Sclerosis" is a retrospective diagnosis which is characterized by 1-2 exacerbations with complete recovery, no lasting disability and no disease progression for 10-15 years after the initial onset. Benign multiple sclerosis may, however, progress into other forms of multiple sclerosis.

15 As used herein, "Relapsing-Relmitting Multiple Sclerosis" (RRMS) is characterized by patients experiencing sporadic exacerbations or relapses, as well as periods of remission. Lesions and evidence of axonal loss may or may not be visible on MRI for patients with RRMS.

20 As used herein, "Secondary Progressive Multiple Sclerosis" (SPMS) is characterized by patients having relapses, a diminishing degree of recovery during remissions, less frequent remissions and more pronounced neurological deficits than RRMS patients. Enlarged ventricles, which are markers for atrophy of the corpus callosum, midline center and spinal cord, are visible on MRI of patients with
25 SPMS.

As used herein, "Primary Progressive Multiple Sclerosis" (PPMS) is characterized by a steady progression of increasing neurological deficits without distinct attacks or remissions. Cerebral lesions,

diffuse spinal cord damage and evidence of axonal loss are evident on the MRI of patients with PPMS.

As used herein, "Progressive-Relapsing Multiple Sclerosis" (PRMS) is characterized by having periods of acute exacerbations while proceeding along a course of increasing neurological deficits without remissions. Lesions are evident on MRI of patients suffering from PRMS.

A clinically isolated syndrome (CIS) is a single monosymptomatic attack compatible with MS, such as optic neuritis, brain stem symptoms, and partial myelitis. Patients with CIS that experience a second clinical attack are generally considered to have clinically definite multiple sclerosis (CDMS). Over 80 percent of patients with a CIS and MRI lesions go on to develop MS, while approximately 20 percent have a self-limited process. (29,30) Patients who experience a single clinical attack consistent with MS may have at least one lesion consistent with multiple sclerosis prior to the development of clinically definite multiple sclerosis.

Multiple sclerosis may present with optic neuritis, blurring of vision, diplopia, involuntary rapid eye movement, blindness, loss of balance, tremors, ataxia, vertigo, clumsiness of a limb, lack of coordination, weakness of one or more extremity, altered muscle tone, muscle stiffness, spasms, tingling, paraesthesia, burning sensations, muscle pains, facial pain, trigeminal neuralgia, stabbing sharp pains, burning tingling pain, slowing of speech, slurring of words, changes in rhythm of speech, dysphagia, fatigue, bladder problems (including urgency, frequency, incomplete emptying and incontinence), bowel problems (including constipation and loss of bowel control), impotence, diminished sexual arousal, loss of sensation, sensitivity to heat, loss of short term memory, loss of concentration, or loss of judgment or reasoning.

The term relapsing MS includes:

- 1) patients with RRMS;
- 2) patients with SPMS and superimposed relapses; and

3) patients with CIS who show lesion dissemination on subsequent MRI scans according to McDonald's criteria.

As used herein, relapsing forms of multiple sclerosis include: Relapsing-remitting multiple sclerosis (RRMS), characterized by unpredictable acute episodes of neurological dysfunction (relapses), followed by variable recovery and periods of clinical stability;

Secondary Progressive MS (SPMS), wherein patients having RRMS develop sustained deterioration with or without relapses superimposed; and

Primary progressive-relapsing multiple sclerosis (PPRMS) or progressive-relapsing multiple sclerosis (PRMS), an uncommon form wherein patients developing a progressive deterioration from the beginning can also develop relapses later on.

A clinical relapse, which may also be used herein as "relapse," "confirmed relapse," or "clinically defined relapse," is defined as the appearance of one or more new neurological abnormalities or the reappearance of one or more previously observed neurological abnormalities.

This change in clinical state must last at least 48 hours and be immediately preceded by a relatively stable or improving neurological state of at least 30 days. This criterion is different from the clinical definition of exacerbation "at least 24 hours duration of symptoms," as detailed in the section "relapse evaluation."

An event is counted as a relapse only when the subject's symptoms are accompanied by observed objective neurological changes, consistent with:

a) an increase of at least 0.5 in the EDSS score or one grade in the score of two or more of the seven FS; or,

b) two grades in the score of one of FS as compared to the previous evaluation.

The subject must not be undergoing any acute metabolic changes such as fever or other medical abnormality. A change in bowel/bladder function

or in cognitive function must not be entirely responsible for the changes in EDSS or FS scores.

As used herein, a "multiple sclerosis drug" is a drug or an agent intended to treat clinically defined MS, CIS, any form of neurodegenerative or demyelinating diseases, or symptoms of any of the above mentioned diseases. "Multiple sclerosis drugs" may include but are not limited to antibodies, immunosuppressants, anti-inflammatory agents, immunomodulators, cytokines, cytotoxic agents and steroids and may include approved drugs, drugs in clinical trial, or alternative treatments, intended to treat clinically defined MS, CIS or any form of neurodegenerative or demyelinating diseases. "Multiple sclerosis drugs" include but are not limited to Interferon and its derivatives (including BETASERON®, AVONEX® and REBIF®), Mitoxantrone and Natalizumab. Agents approved or in-trial for the treatment of other autoimmune diseases, but used in a MS or CIS patient to treat MS or CIS are also defined as multiple sclerosis drugs.

As used herein, a "naïve human" is a human that has not been treated with any multiple sclerosis drug.

As used herein, an "array of testing" for identifying whether a human subject afflicted with multiple sclerosis is a likely responder to glatiramer acetate (GA) therapy includes, but is not limited to, any analytical method test such as *in vitro* tests or biological assays such as the *ex vivo* tests. Examples of identifying whether a human subject afflicted with multiple sclerosis is a likely responder to glatiramer acetate (GA) therapy are disclosed in U.S. Patent Nos. 8,759,302, 8,709,433, and 8,815,511, and U.S. Patent Application No. US 2014-0107208, the disclosures of which are hereby incorporated by reference in their entireties.

As used herein, "about" with regard to a stated number encompasses a range of +10 percent to -10 percent of the stated value. By way of example, about 100 mg therefore includes the range 90-110 mg and therefore also includes 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109 and 110 mg. Accordingly, about 100 mg includes, in an embodiment, 100 mg.

By any range disclosed herein, it is meant that all hundredth, tenth and integer unit amounts within the range are specifically disclosed as part of the invention. Thus, for example, 1 mg to 50 mg means that 1.1, 1.2 . . . 1.9; and 2, 3 . . . 49 mg unit amounts are included as
5 embodiments of this invention.

Each embodiment disclosed herein is contemplated as being applicable to each of the other disclosed embodiments. Thus, all combinations of the various elements described herein are within the scope of the invention.

10 This invention will be better understood by reference to the Experimental Details which follow, but those skilled in the art will readily appreciate that the specific experiments detailed are only illustrative of the invention as described more fully in the claims which follow thereafter.

15 *Patient Subpopulation Can Be Selected Based On Genotypes*

As used herein a SNP or "single nucleotide polymorphism" refers to a specific site in the genome where there is a difference in DNA base between individuals.

Several non-limiting examples of databases from which information on
20 SNPs or genes that are associated with human disease can be retrieved include: NCBI resources, The SNP Consortium LTD, NCBI dbSNP database, International HapMap Project, 1000 Genomes Project, Glovar Variation Browser, SNPStats, PharmGKB, GEN-SniP, and SNPedia.

SNPs are identified herein using the rs identifier numbers in
25 accordance with the NCBI dbSNP database, which is publically available at <URL:ncbi.nlm.nih.gov/projects/SNP/> or using the kgp identifier numbers, which were created by Illumina. Genotype at the kgp SNPs can be obtained by using the Illumina genotyping arrays. In addition, SNPs can be identified by the specific location on the chromosome indicated
30 for the specific SNP.

Additional information about identifying SNPs can be obtained from the NCBI database SNP FAQ archive located at <URL ncbi.nlm.nih.gov/books/NBK3848/> or from literature available on the

Illumina website located at <URL:
illumina.com/applications/genotyping/literature.ilmn>.

A genotype at a position of SNP (genotype "at a" SNP) may be represented by a single letter which corresponds to the identity of the nucleotide at the SNP, where A represents adenine, T represents thymine, C represents cytosine, and G represents guanine. The identity of two alleles at a single SNP may be represented by a two letter combination of A, T, C, and G, where the first letter of the two letter combination represents one allele and the second letter represents the second allele, and where A represents adenine, T represents thymine, C represents cytosine, and G represents guanine. Thus, a two allele genotype at a SNP can be represented as, for example, AA, AT, AG, AC, TT, TG, TC, GG, GC, or CC. It is understood that AT, AG, AC, TG, TC, and GC are equivalent to TA, GA, CA, GT, CT, and CG, respectively.

SNPs can be used as predictive indicators of the response to GA in subjects afflicted with multiple sclerosis. Presence of SNPs can be detected through obtaining a patient DNA sample and evaluating the patient sample for the presence of one or more SNPs, or for a certain set of SNPs. A patient DNA sample can be extracted, and a SNP can be detected in the sample, through any means known to one of ordinary skill in art. Some non-limiting examples of known techniques include detection via restriction fragment length polymorphism (RFLP) analysis, arrays including but not limited to planar microarrays or bead arrays, sequencing, single strand conformation polymorphism analysis (SSCP), chemical cleavage of mismatch (CCM), Polymerase chain reaction (PCR) and denaturing high performance liquid chromatography (DHPLC).

The genotyping array is a whole genome genotyping array. Whole-genome genotyping arrays are arrays that contain hundreds of thousands to millions of genetic sequences (which may also be named "probes").

SNP can be detected through PCR amplification and sequencing of the DNA region comprising the SNP. SNPs can be detected using arrays, exemplified by gene chip, including but not limited to DNA arrays or microarrays, DNA chips, and whole genome genotyping arrays, all of

which may be for example planar arrays or bead arrays, or a TaqMan open Array. Arrays/Microarrays for detection of genetic polymorphisms, changes or mutations (in general, genetic variations) such as a SNP in a DNA sequence, may comprise a solid surface, typically glass, on which a high number of genetic sequences are deposited (the probes), complementary to the genetic variations to be studied. Using standard robotic printers to apply probes to the array a high density of individual probe features can be obtained, for example probe densities of 600 features per cm² or more can be typically achieved. The positioning of probes on an array is precisely controlled by the printing device (robot, inkjet printer, photolithographic mask etc) and probes are aligned in a grid. The organization of probes on the array facilitates the subsequent identification of specific probe-target interactions. Additionally it is common, but not necessary, to divide the array features into smaller sectors, also grid-shaped, that are subsequently referred to as sub-arrays. Sub-arrays typically comprise 32 individual probe features although lower (e.g. 16) or higher (e.g. 64 or more) features can comprise each sub-array. In some arrays the probes are connected to beads instead of the solid support. Such arrays are called "bead arrays" or "bead CHiPs".

Detection of SNP can be achieved by hybridization to sequences which specifically recognize the normal and the mutant allele in a fragment of DNA derived from a test sample. Typically, the fragment has been amplified, e.g. by using the polymerase chain reaction (PCR), and labeled e.g. with a fluorescent molecule. A laser can be used to detect bound labeled fragments on the chip and thus an individual who is homozygous for the normal allele can be specifically distinguished from heterozygous individuals (in the case of autosomal dominant conditions then these individuals are referred to as carriers) or those who are homozygous for the mutant allele. The amplification reaction and/or extension reaction is carried out on the microarray or bead itself. For differential hybridization based methods there are a number of methods for analyzing hybridization data for genotyping:

- Increase in hybridization level: The hybridization levels of probes complementary to the normal and mutant alleles are compared.
- Decrease in hybridization level: Differences in the sequence between a control sample and a test sample can be identified by a decrease in the hybridization level of the totally complementary oligonucleotides with a reference sequence.

A loss approximating 100% is produced in mutant homozygous individuals while there is only an approximately 50% loss in heterozygotes. In Microarrays for examining all the bases of a sequence of "n" nucleotides ("oligonucleotide") of length in both strands, a minimum of "2n" oligonucleotides that overlap with the previous oligonucleotide in all the sequence except in the nucleotide are necessary. Typically the size of the oligonucleotides is about 25 nucleotides. However it should be appreciated that the oligonucleotide can be any length that is appropriate as would be understood by one of ordinary skill in the art. The increased number of oligonucleotides used to reconstruct the sequence reduces errors derived from fluctuation of the hybridization level.

However, the exact change in sequence cannot be identified with this method; this method is combined with sequencing to identify the mutation. Where amplification or extension is carried out on the microarray or bead itself, three methods are presented by way of example: In the Minisequencing strategy, a mutation specific primer is fixed on the slide and after an extension reaction with fluorescent dideoxynucleotides, the image of the Microarray is captured with a scanner. In the Primer extension strategy, two oligonucleotides are designed for detection of the wild type and mutant sequences respectively. The extension reaction is subsequently carried out with one fluorescently labeled nucleotide and the remaining nucleotides unlabelled. In either case the starting material can be either an RNA sample or a DNA product amplified by PCR. In the Tag arrays strategy, an extension reaction is carried out in solution with specific primers, which carry a determined 5' sequence or "tag". The use of Microarrays with oligonucleotides complementary to these sequences or "tags" allows the capture of the resultant products of the extension.

The following abbreviations listed in Table 1 are used herein.

Table 1. Listing of Abbreviations

Abbreviation	Explanation
Abs	Antibodies
ABS	Absorbance
AVG	Average
ELISA	Enzyme-linked Immunosorbent Assay
ET	End of Treatment
GA	Glatiramer Acetate
HRP	Horseradish Peroxidase
ICF	Informed consent form
IgG	Immunoglobuline G
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
NHS	Normal Human Serum pool
NMT	Not More Than
OL	Open Label
PC	Placebo Controlled
QAU	Quality Assurance Unit
RA%	Relative Absorbance %
PBS	Phosphate Buffered Saline
PHS	Positive Human Serum pool
RRMS	Relapsing Remitting Multiple Sclerosis
SST	System Suitability Test
TMB	3,3',5,5'-tetramethylbenzidine

EXPERIMENTAL DETAILS

5 **Example 1**

This report presents the results of anti-Glatiramer Acetate (GA) IgG specific antibodies measurement in human serum samples of a cohort of 262 GA-treated patients tested in the bioanalytical Experimental Phases A, B and C of this study. Patients were derived from 1404
10 patients who participated in the clinical study entitled:

"A multinational, multicenter, randomized, parallel-group study performed in subjects with Relapsing-Remitting Multiple Sclerosis (RRMS) to assess the efficacy, safety and tolerability of Glatiramer

Acetate (GA) injection 40 mg administered three times a week compared to placebo in a double-blind design" (8)

Patients were treated with 40 mg GA by subcutaneous injection three times a week (TIW) for 12 months in placebo controlled (PC) phase, and with the same treatment (40 mg GA by subcutaneous injection three times a week) in an open label extension phase.

- Placebo-Controlled (PC) phase: 12 months of subcutaneous injections of Glatiramer Acetate 40 mg administered either three times a week or a matching placebo injection.
- Open-Label (OL) Extension phase: Subjects completing the PC phase will be offered the opportunity to enter into an open-label (OL) extension phase in which all subjects will continue treatment with GA 40 mg administered three times a week until this dose is commercially available for the treatment of relapsing remitting multiple sclerosis (RRMS) patients or until the development of this GA dose is stopped by the Sponsor. This phase will be of variable duration for each subject, dependent upon when he/she is recruited into the study.

Serum samples, analyzed to detect anti-GA specific IgG antibodies, were collected at months 0 (baseline), 1, 3, 6, 9, 12 (end of PC phase), 18 and 24.

For the measurement of anti-GA specific IgG Abs, an enzyme-linked immunosorbent assay (ELISA) method was used.

Results of 50 baseline samples were used to calculate the study screening cut-point and confirmatory cut-point. The calculated screening cut-point value is 1.4% Relative Absorbance (RA) for this study. The confirmatory cut-point was calculated from OD values of baseline samples spiked with GA relative to the OD values of the same un-spiked samples. The confirmatory cut-point is 50.6%.

All samples of each patient were analyzed in two dilutions (1/500 and 1/1,000) to detect the presence of anti-GA IgG Abs. The screening results of the 1/500 dilution are presented as RA%. The determined RA% of 1740 out of the 1809 non-baseline samples was higher than the

screening cut-point and these were considered as positive in the screening step.

Sample positivity of each screen positive sample of each patient was confirmed in further testing by comparison to the confirmatory cut-point. In the confirmatory tests, samples were tested both with and without GA spiking samples i.e. samples were spiked with GA reference standard to get a final GA concentration of 125 µg/ml in the 1:500 diluted serum. Sample positivity was verified in 99.9% of screen positive non baseline samples.

Confirmed positive samples were further analyzed in a titration test. Ten-fold serial dilutions of the samples were performed on top of the 500 fold dilution described in the method (i.e. starting from 1/500 sample to dilutions of 1/500,000) and the anti-GA IgG Abs titer of each positive sample was determined.

The bioanalytical study consisted testing all time points of 262 patients. The serum samples were screened for anti-GA IgG Abs. All samples which were found screen positive were tested in confirmatory test. The titer of the anti-GA Abs also were determined from all confirmed positive samples.

Study Population

Inclusion Criteria:

Subjects must meet all inclusion criteria in order to be eligible for the study:

1. Subjects must have a confirmed and documented MS diagnosis as defined by the Revised McDonald criteria [Ann Neurol 2005: 58:840-846], with a relapsing-remitting disease course.

2. Subjects must be ambulatory with an EDSS score of 0-5.5 in both screening and baseline visits.

3. Subjects must be in a relapse-free, stable neurological condition and free of corticosteroid treatment [intravenous (IV), intramuscular (IM) and/or per os (PO)] or ACTH (Adrenocorticotrophic hormone) 30 days

prior to screening (month -1) and between screening and baseline (month 0) visits.

4. Subjects must have experienced one of the following:

- At least one documented relapse in the 12 months prior to screening, or
- At least two documented relapses in the 24 months prior to screening, or
- One documented relapse between 12 and 24 months prior to screening with at least one documented T1-Gd enhancing lesion in an MRI performed within 12 months prior to screening.

5. Subjects must be between 18 and 55 years of age, inclusive.

6. Women of child-bearing potential must practice an acceptable method of birth control [acceptable methods of birth control in this study include: surgical sterilization, intrauterine devices, oral contraceptive, contraceptive patch, longacting injectable contraceptive, partner's vasectomy or a double-barrier method (condom or diaphragm with spermicide)].

7. Subjects must be able to sign and date a written informed consent prior to entering the study.

8. Subjects must be willing and able to comply with the protocol requirements for the duration of the study.

Exclusion Criteria:

Any of the following conditions will exclude the subject from entering the study:

1. Subjects with progressive forms of MS.

2. Use of experimental or investigational drugs, and/or participation in drug clinical studies within the 6 months prior to screening.

3. Use of immunosuppressive agents (including Mitoxantrone and Fingolimod) or cytotoxic agents within 6 months prior to the screening visit.

4. Use of natalizumab (Tysabri®) or any other monoclonal antibodies within 2 years prior to screening.
5. Use of cladribine within 2 years prior to screening.
6. Previous treatment with immunomodulators [including IFN β 1a and 1b, and IV Immunoglobulin (IVIg)] within 2 months prior to screening.
7. Previous use of GA or any other glatiramoid.
8. Chronic (more than 30 consecutive days) systemic (IV, PO or IM) corticosteroid treatment within 6 months prior to screening visit.
9. Previous total body irradiation or total lymphoid irradiation.
10. Previous stem-cell treatment, autologous bone marrow transplantation or allogenic bone marrow transplantation.
11. Pregnancy or breastfeeding.
12. Subjects with a clinically significant or unstable medical or surgical condition that would preclude safe and complete study participation, as determined by medical history, physical exams, ECG, abnormal laboratory tests and chest Xray. Such conditions may include hepatic, renal or metabolic diseases, systemic disease, acute infection, current malignancy or recent history (5 years) of malignancy, major psychiatric disorder, history of drug and/or alcohol abuse and allergies that could be detrimental according to the investigator's judgment.
13. A known history of sensitivity to Gadolinium.
14. Inability to successfully undergo MRI scanning.
15. A known drug hypersensitivity to Mannitol.
16. Subjects who underwent endovascular treatment for Chronic Cerebrospinal Venous Insufficiency (CCSVI).

Study Samples

Test samples were generated in a Phase III, parallel-group, double-blind and open label extension study.

Serum samples to detect anti-GA specific antibodies in Experimental Phases A and B were collected at months 0 (baseline), 1, 3, 6, 9, 12 (end of PC phase), 18 and 24 according to the clinical protocol and laboratory manual for the clinical study.

Serum samples were separated into 3 aliquots with sample volume of 0.6 to 0.8 mL per aliquot. All aliquots from each blood collection point were labeled with the following information: "anti-GA serum", study number, patient ID, sample ID. In the Experimental Phases A and B, altogether 2133 serum samples (from 270 patients from GA-treated study group) were analyzed for anti-GA IgG Abs (50 baseline samples were used for cut-point and confirmatory cut-point determination).

No factors which could affect the sample integrity were identified during the transfer and storage of samples at the Biological Testing Department.

Patients, the most time point samples of whom were available, were selected for testing. The analyzed samples derived from 270 patients as follows:

- 1945 samples from 243 patients collected according to clinical protocol at 8 time points, plus an extra sample from patient 601027 at TERMOL/ETOL sampling point

- 188 samples from 27 patients from 7 time points per patient, except for patient 537113 where baseline sample was whole blood instead of serum, and that sample was not analyzed.

Altogether 261 samples at baseline and 1809 samples at different time point after treatment from 262 patients have reportable results.

Determination of anti-GA IgG Antibodies

The purpose was to detect anti-GA specific IgG antibodies in human serum samples obtained from individuals participating in GA clinical studies.

5 Analysis was performed using ELISA. A microtiter plate is coated with GA (Teva Pharmaceutical Industries, Ltd.) reference standard (RS). After washing the excess unbound antigen and blocking the exposed well surface, the human serum samples (in serial dilutions of 1:500 and 1:1000) are added to the GA RS pre-coated wells. Anti-GA IgG antibodies are subsequently detected using a secondary antibody HRP conjugated
10 mouse anti human IgG. Following washing of the excess unbound antibody-enzyme reagent, a substrate solution is added to the wells and color develops in proportion to the amount of anti-GA IgG antibodies in the serum sample.

15 The tested human serum samples are considered as at or above a normal range for the presence of the anti-GA IgG antibodies according to a cut-point. The cut-point is determined for each study from untreated human serum (NHS) samples obtained from the untreated individuals of that study (prior to treatment is administered or placebo subjects) or from untreated individuals from a population that is similar as
20 much as possible to the study population.

Reagents are summarized in Table 2.

Table 2. Reagents Used in Determination of anti-GA IgG Specific Antibodies

REAGENTS	PREPARATION
COATING BUFFER	Dissolve the content of one Carbonate-Bicarbonate buffer capsule in 100 ml of purified water. Mix well on a magnetic stir plate. Adjust the pH to 9.5-9.6 using 1N HCl. Store up to 24 hours at 2°-8 °C.
PHOSPHATE BUFFERED SALINE (PBS)	Dissolve the content of one pouch pre-mixed bag in 1 liter of purified water. Store up to 1 week at 2°-8 °C. Alternatively, sterilize PBS by autoclaving and store unopened up to three months at 2-8 °C.
BLOCKING BUFFER	PBS solution contains 2 % non-fat powdered milk (add 2.0 g of no-fat powdered milk into 100 ml PBS solution). Store up to one week at 2°-8 °C.
WASHING BUFFER (PBST)	PBS solution contains 0.05 % Tween 20 (add 500 µl of Tween 20 into 1000 ml PBS solution). Store up to one week at 2°-8 °C.
SAMPLE BUFFER	PBST contains 0.1 % gelatin and 1 % non-fat powdered milk (Pre-warm 100 ml PBST solution by a hot plate for at least 5 min before adding 100 mg gelatin and 1.0 g milk powders). Store up to one week at 2°-8 °C.
GLATIRAMER ACETATE REFERENCE STANDARD (RS) SOLUTION (1MG/ML)	For example, weigh about 30-40 mg of GA RS lyophilized material and bring to a final concentration of 1.2 mg/ml with purified water. Determine the absorbance of the primary stock solution at 275 nm. The concentration of GA is given by the equation: $\text{Absorbance}_{275 \text{ nm}} \text{ GA } 1.0 \text{ mg/ml} = 1.03$ Based on the determined concentration, correct the volume of the primary stock solution to obtain a solution of 1mg/ml. Divide the GA RS primary stock solution into working aliquots (250 µl/tube). Store at (-10 °C)-(-20 °C) for up to nine months. Use working aliquots once and discard after use.

Prior to performing an assay, allow buffers to reach room temperature.

5 Each plate should include the following samples:

- System suitability Test (SST) - wells coated with purified human IgG.
- SST Blank - wells coated with the blocking buffer only (w/o hIgG and human serum sample). To be subtracted from the SST positive control.
- Positive Human Serum (PHS) - positive human serum pool in dilution of 1/500.
- Negative Human Serum (NHS) - normal human serum pool in dilution of 1/500.

10

- Blank - wells coated with GA (w/o human serum sample). To be subtracted from the NHS & PHS controls and from the human tested serum samples.
- Sample 1 - Sample 13 - different tested serum samples. Each sample applied in two dilutions (1/500 and 1/1000)

All tested human serum samples of different time points from the same individual should be tested (in triplicates), if possible, in the same plate to allow comparison.

For coating, prepare 20 ug/ml GA RS solution by diluting the 200 ul GA RS stock solution in 9.8 ml coating buffer (1:50). Prepare a 1.0ug/ml dilution of hIgG coating antibody and coat the plate at 100 ul/well.

For washing, empty plate and tap out residual liquid, fill each well with 300 ul washing buffer and then invert plate to empty, tap out residual liquid onto paper towel.

For blocking, add 300 ul/well of blocking buffer to each well, seal the plate and incubate at room temperature for 1 hour, and wash the plates three times.

For sample loading, add 100 ul diluted test samples and/or control sample and/or sample buffer to each well. Seal the plate and incubate for 2 hours at room temperature, empty plate, tap out residual liquid and wash three times.

For detection antibody, prepare 1:4000 dilution of the biotinylated anti-hIgG detection antibody by diluting 2.5 ul biotinylated anti-hIgG antibody to 10 ml of blocking buffer. Prepare 10 ml biotinylated anti-human IgG detection antibody solution per plate and add 100 ul of the prepared detection antibodies to each well. Seal the plate and incubate for 1 hour at room temperature. Then empty plate, tap out residual liquid and wash five times.

For streptavidin conjugated horseradish peroxidase (HRP), prepare working dilution of the streptavidin conjugated HRP in blocking buffer. Then add 100 ul/well of the prepared streptavidin conjugated

HRP solution, following shaking the plate for a few seconds. Then incubate the plate for 1 hour at room temperature in the dark, following washing five times.

For enzymatic reaction, TMB (3,3',5,5'-tetramethylbenzidine peroxidase) is used. Mix equal volumes of TMB Peroxidase Substrate (Part 1) and Peroxidase Substrate Solution B in a clean glass container immediately prior to use. Dispense 100 ul of TMB solution into each well and incubate the plate for 15-30 minutes in the dark at 37 °C. Stop the reaction with 100 ul stop solution per well (1N sulphuric acid) and shake the plate for a few seconds. Read the absorbance (ABS) of each well at 450 nm.

Evaluation of triplicates and outlier rejection are performed using SOP for triplicate analysis and outlier rejection in ELISA test. For each triplicates suspected of having an outlier, record all outlier rejection calculations and conclusion.

For blank subtraction, subtract the calculated average absorbance (ABS) of SST blank from average (AVG) ABS value of the SST. Subtract the calculated AVG ABS of blank from AVG ABS value of each test sample including PHS and NHS control samples. All data points that fall below 0.000 are set equal to 0.000.

To overcome plate-to-plate variability, the results are normalized by dividing the absorbance (ABS) of each test sample (including the controls) with that of the SST. This value is the Relative Absorbance (RA) ratio and is multiplied by 100 expressed in percent. These values are the reported response values of the test. The RA value is calculated according to the following equation:

$$RA(\%) = \frac{AVG \text{ test sample ABS} - AVG \text{ Blank ABS}}{AVG \text{ SST ABS} - AVG \text{ SST Blank ABS}} \times 100$$

AVG test sample means AVG ABS of each test sample and/or controls (PHS & NHS).

The RA values of the normal human serum samples obtained from untreated individuals are used to calculate a cut-point value of the test. The cut-point value is used to distinguish between negative and positive

human serum samples. In case that the calculated cut point value of the study is lower than the RA of the detection limit (2*Blank) of the study, the cut point is calculated as follows:

$$RA = \frac{2 * \text{Blank} - \text{Blank}}{\text{SST} - \text{SST Blank}} \times 100$$

5 Plate acceptance criteria is the following:

- The AVG ABS of the blank controls should be not more than (NMT) 20% from that of the SST control.
- The AVG ABS of the SST should be not less than 0.8 at 450 nm.
- 10 • The RA of the negative control (NHS) should be less than or equal to the RA value of the calculated cut point value.
- The RA of the positive control (PHS) should be more than the RA value of the calculated cut point value.
- 15 • In case that one of the test results do not comply with the plate acceptance criteria above, the test is not valid and should be repeated.

A tested human serum sample is considered as positive for the presence of anti-GA IgG antibodies only if in the 1/500 dilution its RA value is higher than the calculated cut-point value of that study. The results of the other dilution (1/1000) will be reported for
20 monitoring, to allow semi quantitative comparison of the tested serum defined as positive.

Serum Controls

Negative human serum pool (NHS) was prepared from 50 baseline samples used for cut point determination. Anti-GA IgG Abs-positive human serum
25 pool (PHS) was prepared from anti-GA IgG Ab positive serum samples of 6 MS (Multiple Sclerosis) patients treated with GA obtained from an earlier clinical study.

Analyses

Each plate included the following controls in triplicate wells:

- 30 • System Suitability Test (SST)

- SST Blank
- Positive human serum (PHS)
- Negative human serum (NHS)
- Reagent Blank

5 In addition to above controls, PHS spiked with GA to get a final GA concentration of 125 µg/ml (in the 1:500 diluted sample) and PHS with solvent were also tested in the same dilution as test samples during the tests of Confirmatory cut-point determination and Confirmation of samples positivity.

10 Sample analyses were performed as follows:

A screening cut-point value and confirmatory cut-point determination:

In order to distinguish positive samples from negative ones in the screening step and to confirm the positivity of the samples, a screening cut-point and a confirmatory cut point were determined.

15 Fifty baseline samples were analyzed unspiked and spiked with 125 µg/ml GA (125 µg/ml GA concentration in the 1:500 diluted sample) according to the Bioanalytical Study Plan in 1/500 dilution. Each sample was analyzed 4 times by two analysts (2 runs each) on two different days.

20 Sample screening:

For the screening analysis, all available time point samples of 270 patients from the GA treated study group were tested in two dilutions (1/500 and 1/1000) in triplicate wells. All samples of each patient were tested on the same plate, whenever it was possible.

25 Confirmation of sample positivity:

Each screen positive sample of each patient was tested both without spiking and with spiking with GA (dissolved in purified water). The final GA concentration in the spiked samples after the 1:500 dilution required by the method was 125 µg/ml. Unspiked and spiked samples were
30 tested according to the method but only in 1/500 dilution.

Anti-GA IgG Abs titer determination:

A titration test for determination of anti-GA IgG Abs titer was performed on all samples whose positivity was confirmed. Ten-fold serial dilutions of the samples were carried out (from 1:500 dilution to dilution of 1/500,000) and were tested according to the method.

5 *Cut-point Calculations*

Screening cut-point calculation:

The purpose of this study is to determine a screening cut-point for anti-GA IgG Ab in human serum samples obtained from untreated individuals in the clinical study. Fifty patients were enrolled to
10 this study and were tested for IgG antibody levels at baseline (pre-treatment).

The calculated screening RA% cut-point was 1.4.

Each sample was tested in two replicates and by two analysts. The four values per individual were averaged to produce the data set used in
15 the following calculations.

The ELISA OD 1/500 dilution readings (ABS) were transformed to percent relative absorbance (RA%) using the following equation:

$$RA(\%) = \frac{AVG \text{ test sample ABS} - AVG \text{ Blank ABS}}{AVG \text{ SST ABS} - AVG \text{ SST Blank ABS}} \times 100$$

The initial distribution of RA% was right skewed with some observed
20 outliers. Clearly, this distribution does not follow the normal distribution model. This distribution's shape suggests the use of a log transformation. After applying the log transformation only one outlier was seen and the null hypothesis assuming normal distribution was not rejected ($P_v = 0.165$). Assuming normal distribution, the 95%
25 quantile on the log scale is 0.370. Using the backwards transformation on this value, yields a cut point of 1.447. In conclusion, the calculated cut-point for RA% of anti-GA IgG antibodies is 1.4%.

Confirmatory cut-point calculation:

The purpose of this study is to determine a confirmatory cut-point
30 for anti-GA IgG Ab in human serum samples obtained from untreated

individuals in the clinical study. Fifty patients were enrolled to this study and were tested for IgG antibody levels at baseline (pre-treatment).

The Confirmatory Cut Point (CCP) and % Inhibition were estimated using the nonparametric 99% percentile of $\ln(\text{Unspiked sample avg. OD} / \text{Spiked sample avg. OD})$. The obtained CCP is 2.024 and the obtained %Inhibition Cut Point is 50.589.

The confirmatory assay is intended to test for specificity of antibody binding by comparing the screening sample without spiked GA to a corresponding sample spiked with GA. The confirmatory cut-point factor is calculated to set the false positive rate at 1%. Reported value (RV) were the unspiked sample avg. ODA and the spiked sample avg. OD. RV were obtained from 50 naïve individuals, each measured 4 times over 2 days by 2 analysts.

The natural logarithmic of the ratio between the unspiked sample avg. OD to spiked sample avg. OD (i.e. $\ln(\text{Unspiked sample avg. OD} / \text{Spiked sample avg. OD})$) was calculated and used for the CCP calculation and % inhibition cut-point.

The %inhibition cut-point is based on the following formula:

$$\% \text{Inhibition} = 100 \times (1 - (1 / \text{CCP}))$$

The four values per individual were averaged to produce the data set used in the CCPs. Since the distribution of $\ln(\text{Unspiked sample avg. OD} / \text{Spiked sample avg. OD})$ is not normally distributed (Shapiro-Wilk $p < 0.0001$) and the skewness is more than 1 the exp (nonparametric 1-alpha percentile of the set $\ln(\text{Unspiked sample avg. OD} / \text{Spiked sample avg. OD})$) was used for the calculation of the cut-point.

The distribution of $\ln(\text{Unspiked sample avg. OD} / \text{Spiked sample avg. OD})$ was right skewed with some observed outliers. Clearly, this distribution does not follow the normal distribution (Shapiro-Wilk = 0.675752, $p < 0.0001$), thus the cut-point is calculated as the nonparametric 99% quantile. The CCP (Unspiked/Spiked) at 99% quantile was 2.024 and the % Inhibition Cut Point was 50.589.

Confirmation of Positivity of Samples

The positivity of a sample for anti-GA IgG antibodies was considered to be confirmed if the calculated percent RA inhibition was higher than the calculated confirmatory cut point (50.6%).

- 5 Percent RA inhibition was calculated according to the following equation:

$$\text{Percent inhibition} = 100 \times (1 - (\text{RA of spiked})/(\text{RA of unspiked}))$$

- 99.9% of the tested screen positive non-baseline samples were found to have higher percent inhibition values than the confirmatory cut-
10 point (50.6%).

Determination of anti-GA IgG Abs Titer

The titer was calculated using the following equation:

Titer of the sample = -log dilution factor of the last dilution that tests positive

- 15 (RA %higher than cut point)

The anti-GA IgG Abs titer was determined for all the confirmed positive samples.

Determination of Annual Relapse Rate

- 20 The annualized relapse rate is defined as the total number of confirmed relapses a patient experienced per year. It is calculated as the total number of confirmed relapses divided by the overall exposure (in years) within the treatment group.

- 25 A complete neurological assessment will be performed at months -1 (screening), 0 (baseline), 3, 6, 9, 12 (end of PC phase). In the OL extension phase, a neurological examination will be performed every 6 months. In addition, a neurological examination will be performed at the termination visit of the OL phase.

A complete neurological assessment will also be performed in the follow-up visits for relapses.

The decision as to whether the neurological change is considered a confirmed relapse will be made by the Treating Neurologist/Physician (or Study Neurologist/Physician as applicable), based on the Converted EDSS or on the FS scores, as assessed by the Examining Neurologist/Physician (or Study Neurologist/Physician as applicable).

Follow-up visits to monitor the course of the relapse will be made at the Treating Neurologist/Physician's (or Study Neurologist/Physician as applicable) discretion and in case of ongoing/un-stabilized relapse within one month following the initial relapse, in addition to the assessment at the next scheduled visit, but the neurological assessments will be performed by the Examining Neurologist/Physician (or Study Neurologist/Physician as applicable).

Viscosity Measurement

The manufacturing process for Copaxone® 40mg/mL was based on the same process used to produce the marketed Copaxone® 20mg/mL, except that aqueous Copaxone® 40mg/mL was filtered at reduced temperature instead of at controlled room temperature prior to being filled into the syringe.

The average viscosity (cPa) of the batches of Copaxone® 40mg/mL were measured using Rheocalc V2.5 Model LV, Spindle CP40, speed 80 rpm, Shear Rate 600 1/sec, Temperature 25°C±0.1.

Osmolality Measurement

The average osmolality (mosmol/Kg) of the batches of Copaxone® 40mg/mL were measured in triplicates.

Results

The number of scheduled and analyzed patient number was 270, but results of 262 were reported. The analyses were performed on altogether 690 plates. Thirty seven of these plates failed because of the following reasons:

- Relative Absorbance (RA%) value of NHS pool sample was higher than the cut-point on 31 screening plates, on 2 confirmatory plates and on 1 titration plate
- the Absorbance (ABS) value of System Suitability Test (SST) sample was higher than the measurement range of the plate reader on 3 confirmatory plates

The samples of the failed plates were retested. All plate control results met the acceptance criteria of the method, in the valid 653 plates of cut-point determination, screening, confirmatory and titration tests.

The average ABS values of the blank controls, i.e. Reagent Blank and SST Blank samples, obtained in 653 plate runs were 0.054 and 0.045, respectively. As shown in Table 3, in all plate runs, the % background of the two blank controls were found to be not more than (NMT) that specified in the method (NMT 20%).

The average ABS of the positive control samples (PHS and SST) were 1.406 and 1.840, respectively. As shown in Table 3, in all 653 plates, the ABS values of the SST were not less than 0.8, as specified in the SST acceptance criterion of the method.

In all the 653 reported plate runs, the RA% values of NHS pool samples were less than or equal to the calculated cut-point (1.4%), and the RA% results of PHS pool samples were higher than the calculated cut-point.

Table 3. Results of Plate Controls

	NHS pool		Blank		SST	SST Blank		PHS	
	ABS	RA%	ABS	%Back	ABS	ABS	%Back	ABS	RA%
Mean	0.064	0.5	0.054	3.0	1.840	0.045	2.5	1.406	76.2
SD	0.014	0.3	0.013	0.9	0.309	0.004	0.5	0.314	17.8
Min	0.041	0.0	0.038	1.5	0.931	0.036	1.2	0.425	29.8
Max	0.155	1.4	0.151	9.4	3.510	0.088	5.5	2.634	199.6

* %Back (%Background) = (ABS value of the blank control / ABS value of the SST) x 100

The results of total of 2070 serum samples from 262 patients were reported for anti-GA IgG Abs. 261 of them were baseline samples, 1809 of them were non-baseline samples (months 1, 3, 6, 9, 12, 18, 24).

The RA% results of the 1/500 diluted samples are shown in Table 4.

5 Based on the RA% values of the 1:500 diluted samples, 1740 out of the 1809 non-baseline samples (96.2%) were found to be higher than the cut-point value (RA% of 1.4).

10 The immunological response profile of the averaged anti-GA IgG response (mean RA% values) in the GA treatment group, is represented in Figure 3. The total antibody level increased at least 50 to 80 RA% within about 3 months from initiation of treatment. The antibody level peaked between about 3 and about 6 months from initiation of treatment and is higher than baseline about 12 months after the initial 40 mg/ml dose of glatiramer acetate. The antibody level increased at a greater
15 rate during the first month compared to the rate of increase after the first month to the third month. As shown in Figure 3, the antibody level after the peak remained low but did not reach the baseline level at month 24.

20 The percent inhibition results and conclusion of confirmatory test are listed in Table 4. The determined titers are also shown in Table 4.

Table 4. Results of Screening of the 1/500 Diluted Samples, Confirmation Test and Anti-GA Antibodies Titer Determination

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
130001	Baseline	SP1	0.054	0.6	Negative					
130001	Month 1	SP1	0.427	23.7	POSITIVE	ConfP-7	99.0	YES	TP211	2.7
130001	Month 3	SP1	2.354	143.1	POSITIVE	ConfP-1	100.0	YES	TP5	3.7
130001	Month 6	SP1	1.265	75.6	POSITIVE	ConfP-7	99.2	YES	TP211	3.7
130001	Month 9	SP1	0.964	57.0	POSITIVE	ConfP-7	99.3	YES	TP211	3.7
130001	Month 12	SP1	1.249	74.6	POSITIVE	ConfP-7	99.5	YES	TP211	3.7
130001	Month 18	SP1	1.752	105.8	POSITIVE	ConfP-7	98.5	YES	TP211	3.7
130001	Month 24	SP1	1.514	91.1	POSITIVE	ConfP-7	98.2	YES	TP211	3.7
130201	Baseline	SP2	0.049	0.1	Negative					
130201	Month 1	SP2	0.675	43.6	POSITIVE	ConfP-7	99.3	YES	TP212	3.7
130201	Month 3	SP2	1.552	104.5	POSITIVE	ConfP-1	99.2	YES	TP5	3.7
130201	Month 6	SP2	0.236	13.1	POSITIVE	ConfP-7	95.5	YES	TP212	2.7
130201	Month 9	SP2	0.824	53.9	POSITIVE	ConfP-7	99.5	YES	TP212	3.7
130201	Month 12	SP2	1.499	100.8	POSITIVE	ConfP-7	99.9	YES	TP212	3.7
130201	Month 18	SP2	0.807	52.7	POSITIVE	ConfP-7	99.8	YES	TP212	3.7
130201	Month 24	SP2	1.016	67.3	POSITIVE	ConfP-7	99.5	YES	TP212	3.7
130304	Baseline	SP3	0.055	0.8	Negative					
130304	Month 1	SP3	2.225	127.2	POSITIVE	ConfP-7	95.1	YES	TP213	4.7
130304	Month 3	SP3	2.522	144.5	POSITIVE	ConfP-1	97.7	YES	TP5	4.7
130304	Month 6	SP3	2.437	139.6	POSITIVE	ConfP-8	90.0	YES	TP213	4.7
130304	Month 9	SP3	2.324	133.0	POSITIVE	ConfP-8	94.4	YES	TP213	4.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
130304	Month 12	SP3	2.230	127.5	POSITIVE	ConfP-8	95.4	YES	TP213	4.7
130304	Month 18	SP3	2.087	119.2	POSITIVE	ConfP-8	94.3	YES	TP213	3.7
130304	Month 24	SP3	1.815	103.3	POSITIVE	ConfP-8	92.0	YES	TP213	3.7
130305	Baseline	SP53	0.050	0.3	Negative					
130305	Month 1	SP53	0.672	31.4	POSITIVE	ConfP-39	98.0	YES	TP14	3.7
130305	Month 3	SP53	2.496	122.5	POSITIVE	ConfP-40	99.5	YES	TP14	4.7
130305	Month 6	SP53	2.606	128.0	POSITIVE	ConfP-40	99.5	YES	TP14	4.7
130305	Month 9	SP53	2.319	113.7	POSITIVE	ConfP-40	99.5	YES	TP14	4.7
130305	Month 12	SP53	1.913	93.4	POSITIVE	ConfP-40	99.7	YES	TP14	3.7
130305	Month 18	SP53	0.224	9.0	POSITIVE	ConfP-40	99.2	YES	TP14	2.7
130305	Month 24	SP53	1.341	64.8	POSITIVE	ConfP-40	99.8	YES	TP15	3.7
130306	Baseline	SP53	0.045	0.1	Negative					
130306	Month 1	SP53	0.370	16.3	POSITIVE	ConfP-40	99.1	YES	TP15	3.7
130306	Month 3	SP53	1.879	91.7	POSITIVE	ConfP-40	99.5	YES	TP15	3.7
130306	Month 6	SP53	0.790	37.3	POSITIVE	ConfP-40	99.4	YES	TP15	3.7
130306	Month 9	SP54	0.284	12.0	POSITIVE	ConfP-41	99.5	YES	TP16	3.7
130306	Month 12	SP54	0.211	8.3	POSITIVE	ConfP-41	98.9	YES	TP17	2.7
130306	Month 18	SP54	0.179	6.7	POSITIVE	ConfP-41	98.3	YES	TP17	2.7
130306	Month 24	SP54	0.102	2.9	POSITIVE	ConfP-41	97.1	YES	TP17	2.7
130307	Baseline	SP54	0.048	0.2	Negative					
130307	Month 1	SP54	0.786	37.0	POSITIVE	ConfP-40	99.5	YES	TP15	3.7
130307	Month 3	SP54	1.511	73.2	POSITIVE	ConfP-40	99.5	YES	TP15	3.7
130307	Month 6	SP54	0.740	34.7	POSITIVE	ConfP-40	99.5	YES	TP16	3.7
130307	Month 9	SP54	0.464	21.0	POSITIVE	ConfP-41	99.5	YES	TP16	3.7
130307	Month 12	SP54	0.822	38.8	POSITIVE	ConfP-41	99.7	YES	TP16	3.7
130307	Month 18	SP54	0.538	24.7	POSITIVE	ConfP-41	99.7	YES	TP16	3.7
130307	Month 24	SP54	0.250	10.3	POSITIVE	ConfP-41	99.4	YES	TP16	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
131301	Baseline	SP191	0.076	0.2	Negative					
131301	Month 1	SP191	0.409	13.5	POSITIVE	ConfP-136	99.1	YES	TP314	2.7
131301	Month 3	SP191	2.612	101.7	POSITIVE	ConfP-136	98.1	YES	TP290	4.7
131301	Month 6					No sample received				
131301	Month 9	SP191	0.521	18.0	POSITIVE	ConfP-136	99.2	YES	TP290	2.7
131301	Month 12	SP191	0.560	19.6	POSITIVE	ConfP-136	99.0	YES	TP290	2.7
131301	Month 18	SP191	0.571	20.0	POSITIVE	ConfP-136	99.4	YES	TP290	2.7
131301	Month 24	SP191	0.522	18.0	POSITIVE	ConfP-136	99.7	YES	TP290	2.7
131501	Baseline	SP3	0.046	0.2	Negative					
131501	Month 1	SP3	0.308	15.5	POSITIVE	ConfP-8	84.8	YES	TP214	2.7
131501	Month 3	SP3	1.998	114.0	POSITIVE	ConfP-1	100.0	YES	TP5	3.7
131501	Month 6	SP3	1.229	69.2	POSITIVE	ConfP-8	94.9	YES	TP214	3.7
131501	Month 9	SP4	0.863	45.8	POSITIVE	ConfP-8	94.4	YES	TP214	3.7
131501	Month 12	SP4	0.388	19.3	POSITIVE	ConfP-8	90.1	YES	TP214	2.7
131501	Month 18	SP4	0.976	52.1	POSITIVE	ConfP-8	96.8	YES	TP214	3.7
131501	Month 24	SP4	1.944	106.0	POSITIVE	ConfP-8	97.8	YES	TP214	3.7
131602	Baseline	SP4	0.049	0.4	Negative					
131602	Month 1	SP4	0.796	42.0	POSITIVE	ConfP-1	100.0	YES	TP5	2.7
131602	Month 3	SP4	0.270	12.7	POSITIVE	ConfP-8	99.1	YES	TP215	2.7
131602	Month 6	SP4	0.114	4.0	POSITIVE	ConfP-8	96.7	YES	TP215	2.7
131602	Month 9	SP4	0.095	3.0	POSITIVE	ConfP-9	99.0	YES	TP215	2.7
131602	Month 12	SP4	0.062	1.1	Negative					
131602	Month 18	SP4	0.122	4.5	POSITIVE	ConfP-9	98.6	YES	TP215	2.7
131602	Month 24	SP4	0.112	3.9	POSITIVE	ConfP-9	97.7	YES	TP215	2.7
132201	Baseline	SP55	0.044	0.3	Negative					
132201	Month 1	SP55	1.466	74.6	POSITIVE	ConfP-41	99.4	YES	TP17	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
132201	Month 3	SP55	1.704	87.0	POSITIVE	ConfP-41	99.7	YES	TP17	3.7
132201	Month 6	SP55	0.512	24.8	POSITIVE	ConfP-41	99.3	YES	TP17	3.7
132201	Month 9	SP55	2.268	116.5	POSITIVE	ConfP-41	99.7	YES	TP18	4.7
132201	Month 12	SP55	1.987	101.8	POSITIVE	ConfP-41	99.8	YES	TP18	3.7
132201	Month 18	SP55	1.991	102.0	POSITIVE	ConfP-42	99.7	YES	TP18	4.7
132201	Month 24	SP55	1.786	91.3	POSITIVE	ConfP-42	99.7	YES	TP18	4.7
132701	Baseline	SP5	0.055	0.5	Negative					
132701	Month 1	SP5	0.177	7.1	POSITIVE	ConfP-9	98.6	YES	TP215	2.7
132701	Month 3	SP5	0.794	40.6	POSITIVE	ConfP-1	99.7	YES	TP5	3.7
132701	Month 6	SP5	0.321	14.9	POSITIVE	ConfP-9	99.1	YES	TP216	2.7
132701	Month 9	SP5	0.271	12.2	POSITIVE	ConfP-9	99.0	YES	TP216	2.7
132701	Month 12	SP5	0.190	7.9	POSITIVE	ConfP-9	98.6	YES	TP216	2.7
132701	Month 18	SP5	0.344	16.2	POSITIVE	ConfP-9	99.1	YES	TP216	3.7
132701	Month 24	SP5	0.359	17.0	POSITIVE	ConfP-9	99.4	YES	TP216	3.7
133501	Baseline	SP5	0.053	0.4	Negative					
133501	Month 1	SP5	1.029	53.3	POSITIVE	ConfP-9	97.0	YES	TP216	3.7
133501	Month 3	SP5	1.873	99.0	POSITIVE	ConfP-1	98.8	YES	TP6	3.7
133501	Month 6	SP5	0.917	47.2	POSITIVE	ConfP-9	96.7	YES	TP217	3.7
133501	Month 9	SP6	0.848	41.2	POSITIVE	ConfP-9	96.2	YES	TP217	3.7
133501	Month 12	SP6	0.532	24.8	POSITIVE	ConfP-9	95.0	YES	TP217	3.7
133501	Month 18	SP6	0.638	30.3	POSITIVE	ConfP-10	99.2	YES	TP217	3.7
133501	Month 24	SP6	0.434	19.7	POSITIVE	ConfP-10	98.2	YES	TP217	3.7
133601	Baseline	SP6	0.046	0.0	Negative					
133601	Month 1	SP6	1.063	52.4	POSITIVE	ConfP-10	99.8	YES	TP217	3.7
133601	Month 3	SP6	2.189	111.0	POSITIVE	ConfP-1	99.9	YES	TP6	3.7
133601	Month 6	SP6	0.479	22.0	POSITIVE	ConfP-10	99.8	YES	TP218	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
133601	Month 9	SP6	1.152	57.0	POSITIVE	ConfP-10	99.7	YES	TP218	3.7
133601	Month 12	SP6	0.865	42.1	POSITIVE	ConfP-10	99.9	YES	TP218	3.7
133601	Month 18	SP6	0.483	22.3	POSITIVE	ConfP-10	99.8	YES	TP218	3.7
133601	Month 24	SP6	0.926	45.3	POSITIVE	ConfP-10	99.7	YES	TP218	3.7
133903	Baseline	SP7	0.044	0.0	Negative					
133903	Month 1	SP7	1.769	83.5	POSITIVE	ConfP-10	99.5	YES	TP218	3.7
133903	Month 3	SP7	2.409	114.5	POSITIVE	ConfP-1	100.0	YES	TP6	3.7
133903	Month 6	SP7	1.361	63.7	POSITIVE	ConfP-10	99.8	YES	TP219	3.7
133903	Month 9	SP7	1.082	50.2	POSITIVE	ConfP-10	99.9	YES	TP219	3.7
133903	Month 12	SP7	0.909	41.8	POSITIVE	ConfP-10	99.7	YES	TP219	3.7
133903	Month 18	SP7	1.014	46.9	POSITIVE	ConfP-10	99.6	YES	TP219	3.7
133903	Month 24	SP7	0.442	19.2	POSITIVE	ConfP-11	99.4	YES	TP219	2.7
134001	Baseline	SP8	0.045	0.0	Negative					
134001	Month 1	SP8	0.048	0.2	Negative					
134001	Month 3	SP8	0.158	5.7	POSITIVE	ConfP-11	97.8	YES	TP219	2.7
134001	Month 6	SP8	0.170	6.3	POSITIVE	ConfP-1	100.0	YES	TP6	2.7
134001	Month 9	SP8	0.069	1.2	Negative					
134001	Month 12	SP8	0.059	0.7	Negative					
134001	Month 18	SP8	0.063	0.9	Negative					
134001	Month 24	SP8	0.050	0.3	Negative					
134602	Baseline	SP55	0.045	0.4	Negative					
134602	Month 1	SP55	0.086	2.5	POSITIVE	ConfP-42	97.6	YES	TP18	2.7
134602	Month 3	SP55	0.737	36.5	POSITIVE	ConfP-42	99.7	YES	TP18	3.7
134602	Month 6	SP55	0.114	4.0	POSITIVE	ConfP-42	98.4	YES	TP19	2.7
134602	Month 9	SP56	0.105	2.6	POSITIVE	ConfP-42	98.2	YES	TP20	2.7
134602	Month 12	SP56	0.112	2.9	POSITIVE	ConfP-43	97.8	YES	TP20	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
134602	Month 18	SP56	0.128	3.6	POSITIVE	ConfP-43	98.4	YES	TP20	2.7
134602	Month 24	SP56	0.167	5.3	POSITIVE	ConfP-43	96.7	YES	TP20	2.7
134701	Baseline	SP56	0.049	0.2	Negative					
134701	Month 1	SP56	0.125	3.5	POSITIVE	ConfP-42	98.6	YES	TP19	2.7
134701	Month 3	SP56	1.810	76.4	POSITIVE	ConfP-42	99.7	YES	TP19	3.7
134701	Month 6	SP56	0.554	22.1	POSITIVE	ConfP-42	99.3	YES	TP19	3.7
134701	Month 9	SP56	0.852	34.9	POSITIVE	ConfP-42	99.7	YES	TP19	3.7
134701	Month 12	SP56	2.183	92.5	POSITIVE	ConfP-42	99.8	YES	TP19	3.7
134701	Month 18	SP56	2.278	96.6	POSITIVE	ConfP-42	99.9	YES	TP20	4.7
134701	Month 24	SP56	2.069	87.6	POSITIVE	ConfP-42	99.8	YES	TP20	3.7
326401	Baseline	SP57	0.044	0.1	Negative					
326401	Month 1	SP57	0.518	28.0	POSITIVE	ConfP-43	99.7	YES	TP21	2.7
326401	Month 3	SP57	1.443	82.6	POSITIVE	ConfP-43	99.0	YES	TP21	3.7
326401	Month 6	SP57	0.225	10.7	POSITIVE	ConfP-43	99.1	YES	TP21	2.7
326401	Month 9	SP57	0.121	4.6	POSITIVE	ConfP-43	97.9	YES	TP21	2.7
326401	Month 12	SP57	0.079	2.1	POSITIVE	ConfP-43	98.4	YES	TP21	2.7
326401	Month 18	SP57	0.077	2.0	POSITIVE	ConfP-43	95.5	YES	TP21	2.7
326401	Month 24	SP57	0.068	1.5	POSITIVE	ConfP-43	98.0	YES	TP22	2.7
327201	Baseline	SP57	0.048	0.3	Negative					
327201	Month 1	SP57	0.639	35.2	POSITIVE	ConfP-43	99.8	YES	TP22	3.7
327201	Month 3	SP57	1.224	69.7	POSITIVE	ConfP-43	99.9	YES	TP22	3.7
327201	Month 6	SP57	0.610	33.5	POSITIVE	ConfP-43	99.6	YES	TP22	3.7
327201	Month 9	SP58	0.888	46.5	POSITIVE	ConfP-44	99.6	YES	TP23	3.7
327201	Month 12	SP58	0.474	23.7	POSITIVE	ConfP-44	99.3	YES	TP24	3.7
327201	Month 18	SP58	0.581	29.6	POSITIVE	ConfP-44	99.6	YES	TP24	3.7
327201	Month 24	SP58	0.480	24.0	POSITIVE	ConfP-44	99.1	YES	TP24	3.7
505201	Baseline	SP59	0.049	0.2	Negative					
505201	Month 1	SP59	0.241	10.9	POSITIVE	ConfP-44	98.3	YES	TP24	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505201	Month 3	SP59	0.495	25.0	POSITIVE	ConfP-44	98.1	YES	TP24	2.7
505201	Month 6	SP59	0.389	19.1	POSITIVE	ConfP-45	99.0	YES	TP24	2.7
505201	Month 9	SP59	0.093	2.6	POSITIVE	ConfP-45	95.6	YES	TP25	2.7
505201	Month 12	SP59	0.097	2.8	POSITIVE	ConfP-45	94.6	YES	TP25	2.7
505201	Month 18	SP59	0.108	3.5	POSITIVE	ConfP-45	95.8	YES	TP25	2.7
505201	Month 24	SP59	0.077	1.7	POSITIVE	ConfP-45	90.0	YES	TP25	2.7
505203	Baseline	SP59	0.056	0.6	Negative					
505203	Month 1	SP59	0.140	5.2	POSITIVE	ConfP-45	92.0	YES	TP25	2.7
505203	Month 3	SP59	0.371	18.1	POSITIVE	ConfP-45	97.0	YES	TP25	2.7
505203	Month 6	SP59	0.298	14.0	POSITIVE	ConfP-45	98.9	YES	TP26	2.7
505203	Month 9	SP60	0.158	6.8	POSITIVE	ConfP-46	96.6	YES	TP27	2.7
505203	Month 12	SP60	0.106	3.7	POSITIVE	ConfP-46	84.6	YES	TP27	2.7
505203	Month 18	SP60	1.303	75.6	POSITIVE	ConfP-46	99.2	YES	TP27	3.7
505203	Month 24	SP60	0.094	2.9	POSITIVE	ConfP-46	89.4	YES	TP27	2.7
505205	Baseline	SP60	0.047	0.1	Negative					
505205	Month 1	SP60	2.586	152.7	POSITIVE	ConfP-45	98.1	YES	TP26	4.7
505205	Month 3	SP60	2.454	144.8	POSITIVE	ConfP-45	98.0	YES	TP26	3.7
505205	Month 6	SP60	2.265	133.4	POSITIVE	ConfP-45	99.0	YES	TP26	3.7
505205	Month 9	SP60	2.245	132.2	POSITIVE	ConfP-45	99.1	YES	TP26	3.7
505205	Month 12	SP60	2.357	138.9	POSITIVE	ConfP-45	99.6	YES	TP26	3.7
505205	Month 18	SP60	1.400	81.4	POSITIVE	ConfP-46	96.8	YES	TP27	3.7
505205	Month 24	SP60	1.727	101.1	POSITIVE	ConfP-46	98.3	YES	TP27	3.7
505207	Baseline	SP61	0.046	0.2	Negative					
505207	Month 1	SP61	0.109	3.2	POSITIVE	ConfP-46	94.3	YES	TP28	2.7
505207	Month 3	SP61	1.109	51.5	POSITIVE	ConfP-46	96.5	YES	TP28	3.7
505207	Month 6	SP61	0.232	9.2	POSITIVE	ConfP-46	99.2	YES	TP28	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505207	Month 9	SP61	0.089	2.3	POSITIVE	ConfP-46	100.0	YES	TP28	2.7
505207	Month 12	SP61	0.092	2.4	POSITIVE	ConfP-46	100.0	YES	TP28	2.7
505207	Month 18	SP61	0.070	1.4	Negative					
505207	Month 24	SP61	0.072	1.4	Negative					
505210	Baseline	SP61	0.048	0.3	Negative					
505210	Month 1	SP61	0.278	11.4	POSITIVE	ConfP-46	100.0	YES	TP28	2.7
505210	Month 3	SP61	0.937	43.2	POSITIVE	ConfP-46	100.0	YES	TP29	3.7
505210	Month 6	SP61	0.153	5.4	POSITIVE	ConfP-47	97.8	YES	TP29	2.7
505210	Month 9	SP62	0.353	14.1	POSITIVE	ConfP-131	98.0	YES	TP283	3.7
505210	Month 12	SP62	0.536	22.5	POSITIVE	ConfP-131	94.4	YES	TP283	3.7
505210	Month 18	SP62	0.449	18.5	POSITIVE	ConfP-131	91.1	YES	TP283	3.7
505210	Month 24	SP62	0.313	12.2	POSITIVE	ConfP-131	85.3	YES	TP283	3.7
505214	Baseline	SP62	0.048	0.0	Negative					
505214	Month 1	SP62	0.127	3.7	POSITIVE	ConfP-131	99.0	YES	TP283	2.7
505214	Month 3	SP62	0.699	30.0	POSITIVE	ConfP-131	99.7	YES	TP283	3.7
505214	Month 6	SP62	0.797	34.5	POSITIVE	ConfP-131	99.1	YES	TP284	3.7
505214	Month 9	SP62	0.218	7.9	POSITIVE	ConfP-131	99.0	YES	TP284	2.7
505214	Month 12	SP62	0.406	16.5	POSITIVE	ConfP-131	99.3	YES	TP284	3.7
505214	Month 18	SP62	0.332	13.1	POSITIVE	ConfP-131	99.4	YES	TP284	3.7
505214	Month 24	SP62	0.261	9.8	POSITIVE	ConfP-131	98.4	YES	TP284	4.7
505301	Baseline	SP63	0.045	0.2	Negative					
505301	Month 1	SP63	1.582	93.1	POSITIVE	ConfP-47	99.0	YES	TP29	3.7
505301	Month 3	SP63	1.918	113.4	POSITIVE	ConfP-47	98.9	YES	TP29	3.7
505301	Month 6	SP63	1.315	77.0	POSITIVE	ConfP-47	98.5	YES	TP29	3.7
505301	Month 9	SP63	0.951	55.0	POSITIVE	ConfP-47	99.1	YES	TP29	3.7
505301	Month 12	SP63	0.453	24.8	POSITIVE	ConfP-47	98.0	YES	TP30	2.7
505301	Month 18	SP63	0.509	28.2	POSITIVE	ConfP-47	97.4	YES	TP30	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505301	Month 24	SP63	0.257	13.0	POSITIVE	ConfP-47	92.3	YES	TP30	2.7
505303	Baseline	SP63	0.045	0.2	Negative					
505303	Month 1	SP63	0.121	4.8	POSITIVE	ConfP-47	99.3	YES	TP30	2.7
505303	Month 3	SP63	1.086	63.1	POSITIVE	ConfP-47	99.6	YES	TP30	3.7
505303	Month 6	SP63	0.187	8.8	POSITIVE	ConfP-47	99.6	YES	TP30	2.7
505303	Month 9	SP64	0.423	23.5	POSITIVE	ConfP-48	99.2	YES	TP32	2.7
505303	Month 12	SP64	0.070	1.7	POSITIVE	ConfP-48	91.8	YES	TP32	2.7
505303	Month 18	SP64	0.544	31.0	POSITIVE	ConfP-48	99.7	YES	TP32	3.7
505303	Month 24	SP64	0.072	1.8	POSITIVE	ConfP-48	95.7	YES	TP32	2.7
505306	Baseline	SP64	0.044	0.1	Negative					
505306	Month 1	SP64	0.130	5.4	POSITIVE	ConfP-47	98.5	YES	TP31	2.7
505306	Month 3	SP64	0.748	43.6	POSITIVE	ConfP-47	99.3	YES	TP31	3.7
505306	Month 6	SP64	0.404	22.3	POSITIVE	ConfP-48	98.9	YES	TP31	2.7
505306	Month 9	SP64	0.103	3.7	POSITIVE	ConfP-48	97.2	YES	TP31	2.7
505306	Month 12	SP64	0.080	2.3	POSITIVE	ConfP-48	94.7	YES	TP31	2.7
505306	Month 18	SP64	0.091	3.0	POSITIVE	ConfP-48	94.2	YES	TP31	2.7
505306	Month 24	SP64	0.089	2.8	POSITIVE	ConfP-48	93.5	YES	TP32	2.7
505307	Baseline	SP65	0.052	0.5	Negative					
505307	Month 1	SP65	2.992	137.5	POSITIVE	ConfP-48	98.6	YES	TP32	4.7
505307	Month 3	SP65	2.889	132.7	POSITIVE	ConfP-48	98.6	YES	TP33	4.7
505307	Month 6	SP65	2.061	94.1	POSITIVE	ConfP-48	98.8	YES	TP33	3.7
505307	Month 9	SP65	1.765	80.3	POSITIVE	ConfP-48	98.9	YES	TP33	3.7
505307	Month 12	SP65	1.442	65.2	POSITIVE	ConfP-49	99.1	YES	TP37	3.7
505307	Month 18	SP65	1.222	55.0	POSITIVE	ConfP-49	99.1	YES	TP33	3.7
505307	Month 24	SP65	0.768	33.8	POSITIVE	ConfP-49	99.2	YES	TP33	3.7
505308	Baseline	SP65	0.048	0.3	Negative					
505308	Month 1	SP65	0.058	0.7	Negative					
505308	Month 3	SP65	0.338	13.8	POSITIVE	ConfP-49	99.1	YES	TP33	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505308	Month 6	SP65	1.514	68.6	POSITIVE	ConfP-49	99.5	YES	TP34	3.7
505308	Month 9	SP66	0.693	32.1	POSITIVE	ConfP-49	99.1	YES	TP35	3.7
505308	Month 12	SP66	0.330	14.0	POSITIVE	ConfP-50	99.6	YES	TP35	2.7
505308	Month 18	SP66	1.091	51.9	POSITIVE	ConfP-50	99.7	YES	TP35	3.7
505308	Month 24	SP66	1.747	84.6	POSITIVE	ConfP-50	99.8	YES	TP35	3.7
505704	Baseline	SP9	0.048	0.2	Negative					
505704	Month 1	SP9	1.916	97.8	POSITIVE	ConfP-11	98.6	YES	TP220	3.7
505704	Month 3	SP9	2.009	102.6	POSITIVE	ConfP-1	99.4	YES	TP6	3.7
505704	Month 6	SP9	1.274	64.2	POSITIVE	ConfP-11	98.0	YES	TP220	2.7
505704	Month 9	SP9	0.892	44.3	POSITIVE	ConfP-11	99.6	YES	TP220	2.7
505704	Month 12	SP9	0.552	26.5	POSITIVE	ConfP-11	97.6	YES	TP220	2.7
505704	Month 18	SP9	0.546	26.2	POSITIVE	ConfP-11	100.0	YES	TP220	2.7
505704	Month 24	SP9	0.478	22.6	POSITIVE	ConfP-11	98.6	YES	TP220	2.7
505705	Baseline	SP197	0.094	0.3	Negative					
505705	Month 1	SP197	0.832	34.0	POSITIVE	ConfP-145	99.2	YES	TP298	3.7
505705	Month 3	SP197	1.122	47.2	POSITIVE	ConfP-145	99.4	YES	TP298	3.7
505705	Month 6	SP197	0.652	25.8	POSITIVE	ConfP-145	98.4	YES	TP298	2.7
505705	Month 9	SP197	0.359	12.4	POSITIVE	ConfP-145	99.2	YES	TP298	2.7
505705	Month 12	SP197	0.323	10.8	POSITIVE	ConfP-145	99.5	YES	TP298	2.7
505705	Month 18					No sample received				
505705	Month 24	SP199	0.161	4.5	POSITIVE	ConfP-145	98.8	YES	TP298	2.7
505706	Baseline	SP9	0.049	0.2	Negative					
505706	Month 1	SP9	0.517	24.7	POSITIVE	ConfP-11	93.1	YES	TP221	2.7
505706	Month 3	SP9	1.273	64.2	POSITIVE	ConfP-1	95.1	YES	TP6	3.7
505706	Month 6	SP9	0.519	24.8	POSITIVE	ConfP-11	95.3	YES	TP221	2.7
505706	Month 9	SP10	0.483	22.5	POSITIVE	ConfP-11	95.2	YES	TP221	2.7
505706	Month 12	SP10	0.413	18.9	POSITIVE	ConfP-11	98.6	YES	TP221	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505706	Month 18	SP10	0.675	32.3	POSITIVE	ConfP-11	98.7	YES	TP221	2.7
505706	Month 24	SP10	0.202	8.1	POSITIVE	ConfP-12	85.8	YES	TP221	2.7
505708	Baseline	SP10	0.050	0.3	Negative					
505708	Month 1	SP10	0.049	0.3	Negative					
505708	Month 3	SP10	1.268	62.6	POSITIVE	ConfP-12	98.8	YES	TP222	3.7
505708	Month 6	SP10	1.360	67.3	POSITIVE	ConfP-1	100.0	YES	TP7	3.7
505708	Month 9	SP10	1.238	61.1	POSITIVE	ConfP-12	98.5	YES	TP222	3.7
505708	Month 12	SP10	0.901	43.9	POSITIVE	ConfP-12	98.0	YES	TP222	2.7
505708	Month 18	SP10	0.626	29.8	POSITIVE	ConfP-12	99.3	YES	TP222	2.7
505708	Month 24	SP10	0.357	16.0	POSITIVE	ConfP-12	93.4	YES	TP222	2.7
505712	Baseline	SP198	0.103	1.0	Negative					
505712	Month 1	SP198	0.222	7.2	POSITIVE	ConfP-146	63.3	YES	TP310	2.7
505712	Month 3	SP198	1.112	53.2	POSITIVE	ConfP-146	92.3	YES	TP310	2.7
505712	Month 6	SP198	0.526	22.9	POSITIVE	ConfP-146	81.9	YES	TP310	2.7
505712	Month 9	SP198	0.390	15.9	POSITIVE	ConfP-146	80.4	YES	TP310	2.7
505712	Month 12	SP198	0.403	16.5	POSITIVE	ConfP-146	77.9	YES	TP310	2.7
505712	Month 18					No sample received				
505712	Month 24	SP198	0.442	18.6	POSITIVE	ConfP-146	98.6	YES	TP310	2.7
505713	Baseline	SP66	0.053	0.2	Negative					
505713	Month 1	SP66	0.286	11.8	POSITIVE	ConfP-49	98.3	YES	TP34	2.7
505713	Month 3	SP66	0.779	36.4	POSITIVE	ConfP-49	99.3	YES	TP34	3.7
505713	Month 6	SP66	0.316	13.3	POSITIVE	ConfP-49	99.2	YES	TP34	2.7
505713	Month 9	SP66	0.970	45.9	POSITIVE	ConfP-49	98.5	YES	TP34	3.7
505713	Month 12	SP66	0.672	31.0	POSITIVE	ConfP-49	98.6	YES	TP34	3.7
505713	Month 18	SP66	0.765	35.7	POSITIVE	ConfP-49	99.0	YES	TP35	3.7
505713	Month 24	SP66	0.494	22.2	POSITIVE	ConfP-49	99.1	YES	TP35	3.7
505717	Baseline	SP67	0.059	0.7	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505717	Month 1	SP67	1.815	88.8	POSITIVE	ConfP-50	98.9	YES	TP36	3.7
505717	Month 3	SP67	1.865	91.4	POSITIVE	ConfP-50	99.3	YES	TP36	3.7
505717	Month 6	SP67	1.668	81.5	POSITIVE	ConfP-50	99.3	YES	TP36	3.7
505717	Month 9	SP67	1.158	55.9	POSITIVE	ConfP-50	99.1	YES	TP36	3.7
505717	Month 12	SP67	1.616	78.9	POSITIVE	ConfP-50	99.4	YES	TP36	3.7
505717	Month 18	SP67	1.318	63.9	POSITIVE	ConfP-50	99.3	YES	TP36	3.7
505717	Month 24	SP67	0.676	31.6	POSITIVE	ConfP-50	99.6	YES	TP37	3.7
505802	Baseline	SP11	0.057	0.8	Negative					
505802	Month 1	SP11	1.505	76.0	POSITIVE	ConfP-12	99.1	YES	TP222	3.7
505802	Month 3	SP11	1.557	78.7	POSITIVE	ConfP-12	98.3	YES	TP223	3.7
505802	Month 6	SP11	1.536	77.7	POSITIVE	ConfP-12	99.5	YES	TP223	3.7
505802	Month 9	SP11	1.677	85.0	POSITIVE	ConfP-12	99.4	YES	TP223	3.7
505802	Month 12	SP11	1.735	88.0	POSITIVE	ConfP-12	99.5	YES	TP223	3.7
505802	Month 18	SP11	1.741	88.3	POSITIVE	ConfP-2	100.0	YES	TP7	3.7
505802	Month 24	SP11	1.390	70.1	POSITIVE	ConfP-12	99.4	YES	TP223	3.7
505806	Baseline	SP11	0.045	0.2	Negative					
505806	Month 1	SP11	1.378	69.4	POSITIVE	ConfP-12	99.9	YES	TP223	3.7
505806	Month 3	SP11	1.568	79.3	POSITIVE	ConfP-2	100.0	YES	TP7	3.7
505806	Month 6	SP11	0.717	35.1	POSITIVE	ConfP-13	99.4	YES	TP224	2.7
505806	Month 9	SP12	0.455	21.4	POSITIVE	ConfP-13	98.0	YES	TP224	2.7
505806	Month 12	SP12	0.313	14.0	POSITIVE	ConfP-13	97.9	YES	TP224	2.7
505806	Month 18	SP12	0.239	10.2	POSITIVE	ConfP-13	98.1	YES	TP224	2.7
505806	Month 24	SP12	0.189	7.6	POSITIVE	ConfP-13	96.7	YES	TP224	2.7
505807	Baseline	SP12	0.088	2.3	POSITIVE	ConfP-13	85.9	YES	TP224	2.7
505807	Month 1	SP12	0.448	21.1	POSITIVE	ConfP-13	91.7	YES	TP225	3.7
505807	Month 3	SP12	1.142	57.2	POSITIVE	ConfP-2	98.7	YES	TP7	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505807	Month 6	SP12	0.756	37.1	POSITIVE	ConfP-13	91.3	YES	TP225	3.7
505807	Month 9	SP12	0.594	28.7	POSITIVE	ConfP-13	86.4	YES	TP225	3.7
505807	Month 12	SP12	0.500	23.8	POSITIVE	ConfP-13	84.4	YES	TP225	3.7
505807	Month 18	SP12	0.378	17.4	POSITIVE	ConfP-13	59.5	YES	TP225	3.7
505807	Month 24	SP12	0.462	21.8	POSITIVE	ConfP-13	58.2	YES	TP225	3.7
505809	Baseline	SP13	0.041	0.0	Negative					
505809	Month 1	SP13	0.597	46.1	POSITIVE	ConfP-13	99.2	YES	TP226	3.7
505809	Month 3	SP13	1.236	99.3	POSITIVE	ConfP-2	100.0	YES	TP7	3.7
505809	Month 6	SP13	0.401	29.8	POSITIVE	ConfP-14	99.3	YES	TP226	3.7
505809	Month 9	SP13	0.685	53.5	POSITIVE	ConfP-14	99.6	YES	TP226	3.7
505809	Month 12	SP13	0.543	41.6	POSITIVE	ConfP-14	99.8	YES	TP226	3.7
505809	Month 18	SP13	0.616	47.7	POSITIVE	ConfP-14	99.8	YES	TP226	2.7
505809	Month 24	SP13	0.156	9.4	POSITIVE	ConfP-14	99.3	YES	TP226	2.7
505810	Baseline	SP67	0.052	0.3	Negative					
505810	Month 1	SP67	0.379	16.7	POSITIVE	ConfP-50	100.0	YES	TP37	2.7
505810	Month 3	SP67	1.056	50.7	POSITIVE	ConfP-50	100.0	YES	TP37	3.7
505810	Month 6	SP67	0.537	24.7	POSITIVE	ConfP-50	99.5	YES	TP41	2.7
505810	Month 9	SP68	0.155	5.5	POSITIVE	ConfP-51	99.1	YES	TP38	2.7
505810	Month 12	SP68	0.081	1.7	POSITIVE	ConfP-51	96.9	YES	TP39	2.7
505810	Month 18	SP68	0.280	12.1	POSITIVE	ConfP-51	99.6	YES	TP39	2.7
505810	Month 24	SP68	0.064	0.8	Negative					
505812	Baseline	SP68	0.067	0.9	Negative					
505812	Month 1	SP68	0.218	8.8	POSITIVE	ConfP-51	97.8	YES	TP37	2.7
505812	Month 3	SP68	1.339	67.4	POSITIVE	ConfP-51	99.5	YES	TP37	3.7
505812	Month 6	SP68	0.861	42.4	POSITIVE	ConfP-51	98.8	YES	TP38	3.7
505812	Month 9	SP68	0.191	7.4	POSITIVE	ConfP-51	98.1	YES	TP38	2.7
505812	Month 12	SP68	0.117	3.6	POSITIVE	ConfP-51	96.6	YES	TP38	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
505812	Month 18	SP68	0.158	5.7	POSITIVE	ConfP-51	95.8	YES	TP38	2.7
505812	Month 24	SP68	0.129	4.2	POSITIVE	ConfP-51	95.1	YES	TP38	2.7
505813	Baseline	SP69	0.046	0.2	Negative					
505813	Month 1	SP69	0.331	16.9	POSITIVE	ConfP-51	98.2	YES	TP39	2.7
505813	Month 3	SP69	1.425	80.8	POSITIVE	ConfP-51	99.2	YES	TP39	3.7
505813	Month 6	SP69	0.325	16.5	POSITIVE	ConfP-51	98.9	YES	TP39	2.7
505813	Month 9	SP69	0.319	16.2	POSITIVE	ConfP-52	98.9	YES	TP39	2.7
505813	Month 12	SP69	0.262	12.9	POSITIVE	ConfP-52	98.6	YES	TP40	2.7
505813	Month 18	SP69	0.212	9.9	POSITIVE	ConfP-52	98.9	YES	TP40	2.7
505813	Month 24	SP69	0.198	9.1	POSITIVE	ConfP-52	98.7	YES	TP40	2.7
505901	Baseline	SP179	0.047	0.3	Negative					
505901	Month 1	SP179	1.990	108.4	POSITIVE	ConfP-129	99.4	YES	TP208	3.7
505901	Month 3	SP179	1.219	65.5	POSITIVE	ConfP-129	99.7	YES	TP208	3.7
505901	Month 6	SP179	1.048	56.0	POSITIVE	ConfP-129	99.7	YES	TP208	3.7
505901	Month 9	SP179	0.173	7.3	POSITIVE	ConfP-130	97.8	YES	TP208	2.7
505901	Month 12	SP179	0.152	6.2	POSITIVE	ConfP-130	97.4	YES	TP209	2.7
505901	Month 18	SP179	0.216	9.7	POSITIVE	ConfP-130	98.0	YES	TP209	2.7
505901	Month 24	SP179	0.168	7.1	POSITIVE	ConfP-130	95.3	YES	TP209	2.7
506003	Baseline	SP69	0.046	0.2	Negative					
506003	Month 1	SP69	0.594	32.3	POSITIVE	ConfP-52	99.4	YES	TP40	2.7
506003	Month 3	SP69	1.897	108.4	POSITIVE	ConfP-52	99.5	YES	TP40	3.7
506003	Month 6	SP69	0.884	49.2	POSITIVE	ConfP-52	99.5	YES	TP40	3.7
506003	Month 9	SP70	0.400	19.0	POSITIVE	ConfP-53	98.8	YES	TP42	2.7
506003	Month 12	SP70	0.476	23.0	POSITIVE	ConfP-53	98.8	YES	TP42	2.7
506003	Month 18	SP70	0.570	28.0	POSITIVE	ConfP-53	99.2	YES	TP42	2.7
506003	Month 24	SP70	1.109	56.7	POSITIVE	ConfP-53	99.6	YES	TP43	3.7
506101	Baseline	SP13	0.043	0.0	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
506101	Month 1	SP13	1.948	158.6	POSITIVE	ConfP-2	100.0	YES	TP7	3.7
506101	Month 3	SP13	1.087	86.9	POSITIVE	ConfP-14	99.7	YES	TP227	3.7
506101	Month 6	SP13	0.444	33.4	POSITIVE	ConfP-14	99.5	YES	TP227	3.7
506101	Month 9	SP14	0.382	25.2	POSITIVE	ConfP-14	99.5	YES	TP227	3.7
506101	Month 12	SP14	0.252	15.6	POSITIVE	ConfP-14	98.6	YES	TP227	2.7
506101	Month 18	SP14	0.234	14.3	POSITIVE	ConfP-14	98.9	YES	TP227	2.7
506101	Month 24	SP14	0.387	25.6	POSITIVE	ConfP-14	99.4	YES	TP227	2.7
506102	Baseline	SP14	0.047	0.5	Negative					
506102	Month 1	SP14	0.104	4.7	POSITIVE	ConfP-14	95.8	YES	TP228	2.7
506102	Month 3	SP14	0.476	32.1	POSITIVE	ConfP-2	100.0	YES	TP8	2.7
506102	Month 6	SP14	0.394	26.1	POSITIVE	ConfP-14	99.1	YES	TP228	3.7
506102	Month 9	SP14	0.221	13.3	POSITIVE	ConfP-15	98.3	YES	TP228	2.7
506102	Month 12	SP14	0.101	4.5	POSITIVE	ConfP-15	97.7	YES	TP228	2.7
506102	Month 18	SP14	0.087	3.5	POSITIVE	ConfP-15	95.7	YES	TP228	2.7
506102	Month 24	SP14	0.078	2.8	POSITIVE	ConfP-15	93.8	YES	TP228	2.7
506105	Baseline	SP15	0.044	0.0	Negative					
506105	Month 1	SP15	0.230	13.1	POSITIVE	ConfP-15	99.4	YES	TP229	3.7
506105	Month 3	SP15	1.122	76.4	POSITIVE	ConfP-2	100.0	YES	TP8	3.7
506105	Month 6	SP15	0.592	38.8	POSITIVE	ConfP-15	99.2	YES	TP229	3.7
506105	Month 9	SP15	0.228	13.0	POSITIVE	ConfP-15	98.5	YES	TP229	2.7
506105	Month 12	SP15	0.266	15.7	POSITIVE	ConfP-15	99.3	YES	TP229	3.7
506105	Month 18	SP15	0.173	9.1	POSITIVE	ConfP-15	99.3	YES	TP229	2.7
506105	Month 24	SP15	0.340	20.9	POSITIVE	ConfP-15	99.8	YES	TP229	3.7
506106	Baseline	SP15	0.043	0.0	Negative					
506106	Month 1	SP15	0.081	2.6	POSITIVE	ConfP-15	98.6	YES	TP230	2.7
506106	Month 3	SP15	0.180	9.6	POSITIVE	ConfP-2	100.0	YES	TP8	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
506106	Month 6	SP15	0.099	3.8	POSITIVE	ConfP-15	97.3	YES	TP230	2.7
506106	Month 9	SP16	0.154	7.4	POSITIVE	ConfP-15	99.1	YES	TP230	2.7
506106	Month 12	SP16	0.088	2.7	POSITIVE	ConfP-16	98.4	YES	TP230	2.7
506106	Month 18	SP16	0.104	3.9	POSITIVE	ConfP-16	98.2	YES	TP230	2.7
506106	Month 24	SP16	0.066	1.2	Negative					
506107	Baseline	SP16	0.052	0.2	Negative					
506107	Month 1	SP16	1.301	87.7	POSITIVE	ConfP-16	99.0	YES	TP230	3.7
506107	Month 3	SP16	1.871	127.6	POSITIVE	ConfP-2	99.1	YES	TP8	3.7
506107	Month 6	SP16	1.098	73.5	POSITIVE	ConfP-16	98.6	YES	TP231	3.7
506107	Month 9	SP16	0.991	66.0	POSITIVE	ConfP-16	98.4	YES	TP231	3.7
506107	Month 12	SP16	0.593	38.1	POSITIVE	ConfP-16	98.3	YES	TP231	3.7
506107	Month 18	SP16	0.573	36.7	POSITIVE	ConfP-16	98.6	YES	TP231	3.7
506107	Month 24	SP16	0.469	29.4	POSITIVE	ConfP-16	98.5	YES	TP231	3.7
506109	Baseline	SP17	0.070	1.9	POSITIVE	ConfP-16	92.9	YES	TP231	2.7
506109	Month 1	SP17	1.506	113.6	POSITIVE	ConfP-2	100.0	YES	TP8	3.7
506109	Month 3	SP17	1.206	90.3	POSITIVE	ConfP-16	99.8	YES	TP232	3.7
506109	Month 6	SP17	0.365	24.9	POSITIVE	ConfP-16	99.7	YES	TP232	3.7
506109	Month 9	SP17	0.226	14.1	POSITIVE	ConfP-16	99.7	YES	TP232	3.7
506109	Month 12	SP17	0.177	10.3	POSITIVE	ConfP-16	99.1	YES	TP232	2.7
506109	Month 18	SP17	0.201	12.1	POSITIVE	ConfP-17	99.7	YES	TP232	3.7
506109	Month 24	SP17	0.122	6.0	POSITIVE	ConfP-17	99.0	YES	TP232	2.7
506111	Baseline	SP70	0.073	1.6	POSITIVE	ConfP-52	33.3	No		
506111	Month 1	SP70	0.714	35.7	POSITIVE	ConfP-52	99.8	YES	TP41	3.7
506111	Month 3	SP70	1.509	78.0	POSITIVE	ConfP-52	99.5	YES	TP41	3.7
506111	Month 6	SP70	0.846	42.7	POSITIVE	ConfP-52	99.1	YES	TP41	3.7
506111	Month 9	SP70	0.523	25.5	POSITIVE	ConfP-52	99.2	YES	TP41	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
506111	Month 12	SP70	0.903	45.7	POSITIVE	ConfP-52	99.3	YES	TP42	3.7
506111	Month 18	SP70	0.842	42.5	POSITIVE	ConfP-53	99.2	YES	TP42	2.7
506111	Month 24	SP70	0.424	20.3	POSITIVE	ConfP-53	98.9	YES	TP42	2.7
506301	Baseline	SP71	0.046	0.2	Negative					
506301	Month 1	SP71	1.500	70.9	POSITIVE	ConfP-53	99.4	YES	TP43	3.7
506301	Month 3	SP71	2.163	103.2	POSITIVE	ConfP-53	99.2	YES	TP43	3.7
506301	Month 6	SP71	1.943	92.5	POSITIVE	ConfP-53	99.1	YES	TP43	3.7
506301	Month 9	SP71	1.386	65.4	POSITIVE	ConfP-53	98.6	YES	TP43	3.7
506301	Month 12	SP71	0.890	41.2	POSITIVE	ConfP-53	98.2	YES	TP43	3.7
506301	Month 18	SP71	1.988	94.6	POSITIVE	ConfP-53	98.8	YES	TP44	3.7
506301	Month 24	SP71	1.279	60.2	POSITIVE	ConfP-53	98.1	YES	TP44	3.7
506302	Baseline	SP71	0.077	1.7	POSITIVE	ConfP-54	44.4	No		
506302	Month 1	SP71	1.083	50.6	POSITIVE	ConfP-54	98.6	YES	TP44	3.7
506302	Month 3	SP71	1.496	70.7	POSITIVE	ConfP-54	99.1	YES	TP44	3.7
506302	Month 6	SP71	0.897	41.6	POSITIVE	ConfP-54	98.2	YES	TP44	2.7
506302	Month 9	SP72	0.825	37.7	POSITIVE	ConfP-54	98.3	YES	TP46	2.7
506302	Month 12	SP72	0.697	31.5	POSITIVE	ConfP-54	97.8	YES	TP46	2.7
506302	Month 18	SP72	0.802	36.6	POSITIVE	ConfP-55	98.3	YES	TP46	2.7
506302	Month 24	SP72	0.873	40.0	POSITIVE	ConfP-55	98.5	YES	TP46	2.7
506303	Baseline	SP72	0.047	0.2	Negative					
506303	Month 1	SP72	0.257	10.4	POSITIVE	ConfP-54	99.1	YES	TP45	2.7
506303	Month 3	SP72	2.161	102.0	POSITIVE	ConfP-54	99.4	YES	TP45	3.7
506303	Month 6	SP72	1.024	47.3	POSITIVE	ConfP-54	98.6	YES	TP45	3.7
506303	Month 9	SP72	0.561	25.0	POSITIVE	ConfP-54	98.6	YES	TP45	2.7
506303	Month 12	SP72	0.336	14.2	POSITIVE	ConfP-54	98.2	YES	TP45	2.7
506303	Month 18	SP72	0.722	32.7	POSITIVE	ConfP-54	98.7	YES	TP45	2.7
506303	Month 24	SP72	0.340	14.3	POSITIVE	ConfP-54	98.6	YES	TP46	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
506305	Baseline	SP73	0.045	0.1	Negative					
506305	Month 1	SP73	0.561	23.1	POSITIVE	ConfP-55	98.5	YES	TP46	2.7
506305	Month 3	SP73	2.236	97.5	POSITIVE	ConfP-55	98.6	YES	TP47	3.7
506305	Month 6	SP73	1.256	53.9	POSITIVE	ConfP-55	99.0	YES	TP47	3.7
506305	Month 9	SP73	0.548	22.5	POSITIVE	ConfP-55	99.0	YES	TP47	2.7
506305	Month 12	SP73	0.843	35.6	POSITIVE	ConfP-55	98.9	YES	TP47	2.7
506305	Month 18	SP73	0.135	4.1	POSITIVE	ConfP-55	97.3	YES	TP47	2.7
506305	Month 24	SP73	0.135	4.1	POSITIVE	ConfP-55	94.7	YES	TP47	2.7
506401	Baseline	SP73	0.044	0.1	Negative					
506401	Month 1	SP73	2.512	109.7	POSITIVE	ConfP-55	99.4	YES	TP48	4.7
506401	Month 3	SP73	1.988	86.5	POSITIVE	ConfP-55	99.6	YES	TP48	3.7
506401	Month 6	SP73	0.315	12.1	POSITIVE	ConfP-55	99.0	YES	TP48	2.7
506401	Month 9	SP74	0.297	12.5	POSITIVE	ConfP-56	98.9	YES	TP49	2.7
506401	Month 12	SP74	0.345	14.8	POSITIVE	ConfP-56	98.8	YES	TP49	2.7
506401	Month 18	SP74	0.481	21.4	POSITIVE	ConfP-56	98.9	YES	TP50	2.7
506401	Month 24	SP74	0.839	38.9	POSITIVE	ConfP-56	99.5	YES	TP50	3.7
513201	Baseline	SP75	0.054	0.5	Negative					
513201	Month 1	SP75	0.143	5.0	POSITIVE	ConfP-57	98.3	YES	TP51	2.7
513201	Month 3	SP75	0.859	40.6	POSITIVE	ConfP-57	98.5	YES	TP51	3.7
513201	Month 6	SP75	0.429	19.2	POSITIVE	ConfP-57	95.6	YES	TP51	3.7
513201	Month 9	SP76	0.330	14.0	POSITIVE	ConfP-58	96.8	YES	TP53	2.7
513201	Month 12	SP76	0.105	3.0	POSITIVE	ConfP-58	97.5	YES	TP53	2.7
513201	Month 18	SP76	0.132	4.3	POSITIVE	ConfP-58	90.3	YES	TP53	2.7
513201	Month 24	SP76	0.087	2.1	POSITIVE	ConfP-58	89.5	YES	TP53	2.7
513202	Baseline	SP76	0.046	0.1	Negative					
513202	Month 1	SP76	2.059	98.5	POSITIVE	ConfP-57	99.0	YES	TP52	3.7
513202	Month 3	SP76	1.115	52.3	POSITIVE	ConfP-57	98.9	YES	TP52	3.7
513202	Month 6	SP76	0.698	32.0	POSITIVE	ConfP-57	99.4	YES	TP52	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
513202	Month 9	SP76	0.282	11.6	POSITIVE	ConfP-57	98.8	YES	TP52	2.7
513202	Month 12	SP76	0.323	13.6	POSITIVE	ConfP-57	98.5	YES	TP52	2.7
513202	Month 18	SP76	0.493	21.9	POSITIVE	ConfP-57	94.5	YES	TP52	2.7
513202	Month 24	SP76	0.113	3.4	POSITIVE	ConfP-58	96.7	YES	TP53	2.7
513204	Baseline	SP77	0.045	0.2	Negative					
513204	Month 1	SP77	0.132	6.3	POSITIVE	ConfP-58	100.0	YES	TP53	2.7
513204	Month 3	SP77	0.302	18.2	POSITIVE	ConfP-58	100.0	YES	TP54	2.7
513204	Month 6	SP77	0.073	2.2	POSITIVE	ConfP-58	100.0	YES	TP54	2.7
513204	Month 9	SP77	0.070	2.0	POSITIVE	ConfP-58	96.4	YES	TP54	2.7
513204	Month 12	SP77	0.096	3.8	POSITIVE	ConfP-58	100.0	YES	TP54	2.7
513204	Month 18	SP77	0.058	1.1	Negative					
513204	Month 24	SP77	0.086	3.1	POSITIVE	ConfP-58	100.0	YES	TP54	2.7
522001	Baseline	SP183	0.061	1.3	Negative					
522001	Month 1	SP183	0.747	47.4	POSITIVE	ConfP-132	98.2	YES	TP285	3.7
522001	Month 3	SP183	0.910	58.4	POSITIVE	ConfP-132	97.4	YES	TP286	3.7
522001	Month 6	SP183	0.894	57.3	POSITIVE	ConfP-132	96.8	YES	TP286	3.7
522001	Month 9	SP183	0.905	58.0	POSITIVE	ConfP-132	97.6	YES	TP286	3.7
522001	Month 12	SP183	0.951	61.1	POSITIVE	ConfP-132	96.8	YES	TP286	3.7
522001	Month 18	SP183	0.606	37.9	POSITIVE	ConfP-132	96.3	YES	TP286	3.7
522001	Month 24	SP183	0.419	25.4	POSITIVE	ConfP-132	95.9	YES	TP286	3.7
522201	Baseline	SP77	0.050	0.6	Negative					
522201	Month 1	SP77	0.415	26.1	POSITIVE	ConfP-58	100.0	YES	TP54	2.7
522201	Month 3	SP77	1.716	117.2	POSITIVE	ConfP-58	99.7	YES	TP55	3.7
522201	Month 6	SP77	0.370	23.0	POSITIVE	ConfP-59	99.7	YES	TP55	2.7
522201	Month 9	SP78	0.452	25.3	POSITIVE	ConfP-59	99.5	YES	TP56	3.7
522201	Month 12	SP78	0.651	37.5	POSITIVE	ConfP-59	99.0	YES	TP56	3.7
522201	Month 18	SP78	0.511	28.9	POSITIVE	ConfP-59	99.2	YES	TP56	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
522201	Month 24	SP78	0.536	30.5	POSITIVE	ConfP-59	99.0	YES	TP57	3.7
522205	Baseline	SP78	0.045	0.4	Negative					
522205	Month 1	SP78	0.265	13.8	POSITIVE	ConfP-59	99.6	YES	TP55	2.7
522205	Month 3	SP78	0.809	47.2	POSITIVE	ConfP-59	99.7	YES	TP55	3.7
522205	Month 6	SP78	0.426	23.7	POSITIVE	ConfP-59	99.4	YES	TP55	2.7
522205	Month 9	SP78	0.306	16.4	POSITIVE	ConfP-59	99.7	YES	TP55	2.7
522205	Month 12	SP78	0.402	22.2	POSITIVE	ConfP-59	99.6	YES	TP56	3.7
522205	Month 18	SP78	0.471	26.5	POSITIVE	ConfP-59	99.1	YES	TP56	2.7
522205	Month 24	SP78	0.351	19.1	POSITIVE	ConfP-59	99.3	YES	TP56	3.7
522401	Baseline	SP79	0.046	0.0	Negative					
522401	Month 1	SP79	0.689	35.0	POSITIVE	ConfP-59	99.5	YES	TP57	2.7
522401	Month 3	SP79	1.833	97.6	POSITIVE	ConfP-60	99.5	YES	TP57	3.7
522401	Month 6	SP79	1.579	83.7	POSITIVE	ConfP-60	99.6	YES	TP57	3.7
522401	Month 9	SP79	0.929	48.2	POSITIVE	ConfP-60	99.5	YES	TP57	3.7
522401	Month 12	SP79	0.284	12.9	POSITIVE	ConfP-60	99.7	YES	TP57	2.7
522401	Month 18	SP79	0.621	31.3	POSITIVE	ConfP-60	99.6	YES	TP58	2.7
522401	Month 24	SP79	0.274	12.4	POSITIVE	ConfP-60	99.7	YES	TP58	2.7
522402	Baseline	SP79	0.045	0.0	Negative					
522402	Month 1	SP79	0.070	1.2	Negative					
522402	Month 3	SP79	1.364	72.0	POSITIVE	ConfP-60	99.7	YES	TP58	3.7
522402	Month 6	SP79	0.387	18.5	POSITIVE	ConfP-60	99.5	YES	TP58	2.7
522402	Month 9	SP80	0.208	9.8	POSITIVE	ConfP-61	99.0	YES	TP59	2.7
522402	Month 12	SP80	0.122	4.6	POSITIVE	ConfP-61	99.4	YES	TP59	2.7
522402	Month 18	SP80	0.083	2.3	POSITIVE	ConfP-61	99.0	YES	TP59	2.7
522402	Month 24	SP80	0.057	0.7	Negative					
522403	Baseline	SP80	0.055	0.6	Negative					
522403	Month 1	SP80	0.079	2.0	POSITIVE	ConfP-60	63.2	YES	TP58	2.7
522403	Month 3	SP80	0.861	49.2	POSITIVE	ConfP-60	97.1	YES	TP58	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
522403	Month 6	SP80	0.129	5.1	POSITIVE	ConfP-60	90.2	YES	TP59	2.7
522403	Month 9	SP80	0.125	4.8	POSITIVE	ConfP-60	91.8	YES	TP59	2.7
522403	Month 12	SP80	0.199	9.3	POSITIVE	ConfP-60	96.1	YES	TP59	2.7
522403	Month 18	SP80	0.069	1.4	Negative					
522403	Month 24	SP80	0.046	0.1	Negative					
522404	Baseline	SP81	0.053	0.4	Negative					
522404	Month 1	SP81	0.843	28.6	POSITIVE	ConfP-61	99.6	YES	TP60	3.7
522404	Month 3	SP81	1.845	64.3	POSITIVE	ConfP-61	99.7	YES	TP60	3.7
522404	Month 6	SP81	0.704	23.6	POSITIVE	ConfP-61	99.0	YES	TP60	2.7
522404	Month 9	SP81	0.586	19.4	POSITIVE	ConfP-61	99.5	YES	TP60	2.7
522404	Month 12	SP81	1.650	57.3	POSITIVE	ConfP-61	99.6	YES	TP60	3.7
522404	Month 18	SP81	0.467	15.2	POSITIVE	ConfP-61	99.4	YES	TP60	2.7
522404	Month 24	SP81	0.658	22.0	POSITIVE	ConfP-61	99.5	YES	TP61	2.7
522410	Baseline	SP81	0.052	0.4	Negative					
522410	Month 1	SP81	0.157	4.1	POSITIVE	ConfP-61	99.1	YES	TP61	2.7
522410	Month 3	SP81	0.299	9.2	POSITIVE	ConfP-61	99.6	YES	TP61	2.7
522410	Month 6	SP81	0.232	6.8	POSITIVE	ConfP-61	97.2	YES	TP61	2.7
522410	Month 9	SP82	0.296	10.8	POSITIVE	ConfP-62	98.4	YES	TP62	2.7
522410	Month 12	SP82	0.590	23.3	POSITIVE	ConfP-62	99.1	YES	TP63	2.7
522410	Month 18	SP82	0.636	25.3	POSITIVE	ConfP-62	98.6	YES	TP63	2.7
522410	Month 24	SP82	0.707	28.3	POSITIVE	ConfP-62	97.8	YES	TP63	2.7
536601	Baseline	SP82	0.053	0.5	Negative					
536601	Month 1	SP82	1.161	47.7	POSITIVE	ConfP-62	99.8	YES	TP61	3.7
536601	Month 3	SP82	1.243	51.1	POSITIVE	ConfP-62	99.7	YES	TP61	3.7
536601	Month 6	SP82	0.294	10.7	POSITIVE	ConfP-62	99.0	YES	TP62	2.7
536601	Month 9	SP82	0.122	3.4	POSITIVE	ConfP-62	98.9	YES	TP62	2.7
536601	Month 12	SP82	0.110	2.9	POSITIVE	ConfP-62	98.6	YES	TP62	2.7
536601	Month 18	SP82	0.090	2.0	POSITIVE	ConfP-62	97.7	YES	TP62	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536601	Month 24	SP82	0.103	2.6	POSITIVE	ConfP-62	96.7	YES	TP62	2.7
536603	Baseline	SP83	0.046	0.0	Negative					
536603	Month 1	SP83	0.096	2.3	POSITIVE	ConfP-62	95.9	YES	TP63	2.7
536603	Month 3	SP83	0.862	38.0	POSITIVE	ConfP-62	98.6	YES	TP63	3.7
536603	Month 6	SP83	0.643	27.8	POSITIVE	ConfP-63	99.5	YES	TP63	2.7
536603	Month 9	SP83	0.346	13.9	POSITIVE	ConfP-63	99.8	YES	TP64	3.7
536603	Month 12	SP83	0.275	10.6	POSITIVE	ConfP-63	99.4	YES	TP64	2.7
536603	Month 18	SP83	0.227	8.4	POSITIVE	ConfP-63	99.2	YES	TP64	2.7
536603	Month 24	SP83	0.246	9.3	POSITIVE	ConfP-63	98.8	YES	TP64	2.7
536604	Baseline	SP185	0.077	0.2	Negative					
536604	Month 1					No sample received				
536604	Month 3	SP185	0.744	33.0	POSITIVE	ConfP-137	99.7	YES	TP314	3.7
536604	Month 6	SP185	0.941	42.6	POSITIVE	ConfP-137	98.7	YES	TP290	3.7
536604	Month 9	SP185	0.800	35.7	POSITIVE	ConfP-137	98.0	YES	TP291	2.7
536604	Month 12	SP185	0.469	19.5	POSITIVE	ConfP-137	97.4	YES	TP291	2.7
536604	Month 18	SP185	0.283	10.3	POSITIVE	ConfP-137	98.4	YES	TP291	2.7
536604	Month 24	SP185	0.246	8.5	POSITIVE	ConfP-137	97.2	YES	TP291	2.7
536701	Baseline	SP83	0.046	0.0	Negative					
536701	Month 1	SP83	0.370	15.1	POSITIVE	ConfP-63	99.5	YES	TP64	2.7
536701	Month 3	SP83	1.432	64.6	POSITIVE	ConfP-63	99.8	YES	TP64	3.7
536701	Month 6	SP83	0.866	38.2	POSITIVE	ConfP-63	99.5	YES	TP65	3.7
536701	Month 9	SP84	0.467	20.4	POSITIVE	ConfP-64	99.3	YES	TP66	3.7
536701	Month 12	SP84	0.530	23.4	POSITIVE	ConfP-64	99.3	YES	TP66	3.7
536701	Month 18	SP84	0.581	25.9	POSITIVE	ConfP-64	97.2	YES	TP66	3.7
536701	Month 24	SP84	0.568	25.3	POSITIVE	ConfP-64	97.6	YES	TP66	3.7
536702	Baseline	SP84	0.050	0.4	Negative					
536702	Month 1	SP84	0.519	22.9	POSITIVE	ConfP-63	99.1	YES	TP65	3.7
536702	Month 3	SP84	1.842	86.4	POSITIVE	ConfP-63	99.8	YES	TP65	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536702	Month 6	SP84	0.638	28.6	POSITIVE	ConfP-63	99.5	YES	TP65	3.7
536702	Month 9	SP84	0.787	35.8	POSITIVE	ConfP-63	99.2	YES	TP65	3.7
536702	Month 12	SP84	0.605	27.0	POSITIVE	ConfP-63	99.5	YES	TP65	3.7
536702	Month 18	SP84	0.344	14.5	POSITIVE	ConfP-64	98.8	YES	TP66	2.7
536702	Month 24	SP84	0.428	18.5	POSITIVE	ConfP-64	99.4	YES	TP66	2.7
536703	Baseline	SP85	0.046	0.1	Negative					
536703	Month 1	SP85	2.417	118.9	POSITIVE	ConfP-64	97.9	YES	TP67	4.7
536703	Month 3	SP85	2.358	115.9	POSITIVE	ConfP-64	98.2	YES	TP67	4.7
536703	Month 6	SP85	1.351	65.5	POSITIVE	ConfP-64	99.4	YES	TP67	3.7
536703	Month 9	SP85	0.649	30.3	POSITIVE	ConfP-64	99.3	YES	TP67	3.7
536703	Month 12	SP85	0.398	17.7	POSITIVE	ConfP-64	99.1	YES	TP67	2.7
536703	Month 18	SP85	0.492	22.4	POSITIVE	ConfP-64	98.5	YES	TP67	3.7
536703	Month 24	SP85	0.477	21.7	POSITIVE	ConfP-64	98.6	YES	TP68	2.7
536704	Baseline	SP85	0.044	0.0	Negative					
536704	Month 1	SP85	0.049	0.2	Negative					
536704	Month 3	SP85	0.334	14.5	POSITIVE	ConfP-65	96.3	YES	TP68	2.7
536704	Month 6	SP85	0.444	20.0	POSITIVE	ConfP-65	99.1	YES	TP68	3.7
536704	Month 9	SP86	0.134	4.9	POSITIVE	ConfP-65	97.6	YES	TP69	2.7
536704	Month 12	SP86	0.184	7.7	POSITIVE	ConfP-65	97.8	YES	TP69	2.7
536704	Month 18	SP86	0.072	1.6	POSITIVE	ConfP-65	92.2	YES	TP69	2.7
536704	Month 24	SP86	0.086	2.3	POSITIVE	ConfP-65	97.1	YES	TP69	2.7
536707	Baseline	SP86	0.052	0.5	Negative					
536707	Month 1	SP86	0.060	0.9	Negative					
536707	Month 3	SP86	0.282	13.0	POSITIVE	ConfP-65	99.2	YES	TP68	3.7
536707	Month 6	SP86	0.176	7.2	POSITIVE	ConfP-65	100.0	YES	TP68	2.7
536707	Month 9	SP184	0.322	17.7	POSITIVE	ConfP-132	97.5	YES	TP387	2.7
536707	Month 12	SP86	0.526	26.2	POSITIVE	ConfP-65	98.2	YES	TP68	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536707	Month 18	SP86	0.261	11.8	POSITIVE	ConfP-65	93.9	YES	TP69	2.7
536707	Month 24	SP86	0.367	17.6	POSITIVE	ConfP-65	97.2	YES	TP69	2.7
536708	Baseline	SP87	0.050	0.4	Negative					
536708	Month 1	SP87	0.933	54.1	POSITIVE	ConfP-65	99.5	YES	TP70	3.7
536708	Month 3	SP87	2.002	119.2	POSITIVE	ConfP-65	99.1	YES	TP70	3.7
536708	Month 6	SP87	0.980	57.0	POSITIVE	ConfP-66	97.6	YES	TP70	3.7
536708	Month 9	SP87	0.623	35.2	POSITIVE	ConfP-66	98.2	YES	TP70	3.7
536708	Month 12	SP87	0.354	18.9	POSITIVE	ConfP-66	98.2	YES	TP70	2.7
536708	Month 18	SP87	0.709	40.5	POSITIVE	ConfP-66	98.9	YES	TP70	3.7
536708	Month 24	SP87	0.212	10.2	POSITIVE	ConfP-66	96.6	YES	TP71	2.7
536709	Baseline	SP87	0.047	0.2	Negative					
536709	Month 1	SP87	1.695	100.5	POSITIVE	ConfP-66	98.7	YES	TP71	3.7
536709	Month 3	SP87	2.290	136.7	POSITIVE	ConfP-66	98.6	YES	TP71	4.7
536709	Month 6	SP87	2.086	124.3	POSITIVE	ConfP-66	99.3	YES	TP71	3.7
536709	Month 9	SP88	1.818	96.4	POSITIVE	ConfP-67	99.6	YES	TP72	4.7
536709	Month 12	SP88	1.500	79.0	POSITIVE	ConfP-67	99.5	YES	TP73	3.7
536709	Month 18	SP88	1.221	63.7	POSITIVE	ConfP-67	98.4	YES	TP73	3.7
536709	Month 24	SP88	0.679	34.0	POSITIVE	ConfP-67	98.9	YES	TP73	3.7
536804	Baseline	SP88	0.046	0.0	Negative					
536804	Month 1	SP88	1.682	89.0	POSITIVE	ConfP-66	99.5	YES	TP71	3.7
536804	Month 3	SP88	1.305	68.3	POSITIVE	ConfP-66	99.7	YES	TP71	3.7
536804	Month 6	SP88	0.824	41.9	POSITIVE	ConfP-66	99.5	YES	TP72	3.7
536804	Month 9	SP88	0.514	24.9	POSITIVE	ConfP-66	99.6	YES	TP72	3.7
536804	Month 12	SP88	0.454	21.7	POSITIVE	ConfP-66	98.5	YES	TP72	3.7
536804	Month 18	SP88	0.332	15.0	POSITIVE	ConfP-67	98.2	YES	TP72	2.7
536804	Month 24	SP88	0.383	17.8	POSITIVE	ConfP-67	98.3	YES	TP72	3.7
536805	Baseline	SP102	0.052	0.8	Negative					
536805	Month 1	SP102	0.391	29.6	POSITIVE	ConfP-77	98.4	YES	TP94	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536805	Month 3	SP102	1.787	148.0	POSITIVE	ConfP-77	98.0	YES	TP94	3.7
536805	Month 6	SP102	1.298	106.5	POSITIVE	ConfP-77	98.5	YES	TP94	3.7
536805	Month 9	SP102	0.975	79.1	POSITIVE	ConfP-77	99.1	YES	TP94	3.7
536805	Month 12	SP102	0.786	63.1	POSITIVE	ConfP-77	98.6	YES	TP94	3.7
536805	Month 18	SP102	0.137	8.1	POSITIVE	ConfP-77	96.9	YES	TP95	2.7
536805	Month 24	SP102	0.063	1.8	POSITIVE	ConfP-77	90.5	YES	TP95	2.7
536806	Baseline	SP101	0.044	0.2	Negative					
536806	Month 1	SP101	0.050	0.7	Negative					
536806	Month 3	SP101	0.530	41.6	POSITIVE	ConfP-76	98.3	YES	TP93	3.7
536806	Month 6	SP101	1.068	87.5	POSITIVE	ConfP-76	99.0	YES	TP94	3.7
536806	Month 9	SP102	0.841	67.8	POSITIVE	ConfP-77	99.4	YES	TP95	3.7
536806	Month 12	SP102	0.875	70.7	POSITIVE	ConfP-77	99.5	YES	TP95	3.7
536806	Month 18	SP102	0.395	29.9	POSITIVE	ConfP-77	99.4	YES	TP95	3.7
536806	Month 24	SP102	0.310	22.7	POSITIVE	ConfP-77	99.7	YES	TP95	2.7
536807	Baseline	SP101	0.047	0.4	Negative					
536807	Month 1	SP101	0.382	29.0	POSITIVE	ConfP-76	99.0	YES	TP92	3.7
536807	Month 3	SP101	0.916	74.6	POSITIVE	ConfP-76	99.0	YES	TP92	3.7
536807	Month 6	SP101	0.876	71.2	POSITIVE	ConfP-76	98.6	YES	TP93	3.7
536807	Month 9	SP101	0.492	38.4	POSITIVE	ConfP-76	98.9	YES	TP93	3.7
536807	Month 12	SP101	0.735	59.1	POSITIVE	ConfP-76	99.4	YES	TP93	3.7
536807	Month 18	SP101	0.395	30.1	POSITIVE	ConfP-76	99.1	YES	TP93	3.7
536807	Month 24	SP101	0.875	71.1	POSITIVE	ConfP-76	98.3	YES	TP93	3.7
536808	Baseline	SP104	0.050	0.0	Negative					
536808	Month 1	SP104	1.719	133.7	POSITIVE	ConfP-78	98.0	YES	TP97	4.7
536808	Month 3	SP104	2.295	179.8	POSITIVE	ConfP-78	98.1	YES	TP97	4.7
536808	Month 6	SP104	1.797	139.9	POSITIVE	ConfP-78	99.7	YES	TP98	3.7
536808	Month 9	SP104	2.153	168.4	POSITIVE	ConfP-78	99.7	YES	TP98	4.7
536808	Month 12	SP104	0.772	57.8	POSITIVE	ConfP-78	99.7	YES	TP98	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536808	Month 18	SP104	2.103	164.4	POSITIVE	ConfP-79	97.4	YES	TP98	4.7
536808	Month 24	SP104	2.181	170.7	POSITIVE	ConfP-79	97.4	YES	TP98	4.7
536811	Baseline	SP103	0.048	0.5	Negative					
536811	Month 1	SP103	0.138	7.6	POSITIVE	ConfP-78	99.3	YES	TP97	2.7
536811	Month 3	SP103	0.363	25.5	POSITIVE	ConfP-78	99.4	YES	TP97	3.7
536811	Month 6	SP103	0.176	10.7	POSITIVE	ConfP-78	98.6	YES	TP97	2.7
536811	Month 9	SP104	0.120	5.5	POSITIVE	ConfP-79	94.6	YES	TP98	2.7
536811	Month 12	SP104	0.071	1.6	POSITIVE	ConfP-79	91.3	YES	TP99	2.7
536811	Month 18	SP104	0.068	1.4	Negative					
536811	Month 24	SP104	0.066	1.2	Negative					
536901	Baseline	SP17	0.047	0.2	Negative					
536901	Month 1	SP17	0.371	25.3	POSITIVE	ConfP-17	99.8	YES	TP233	3.7
536901	Month 3	SP17	1.293	97.0	POSITIVE	ConfP-2	100.0	YES	TP8	3.7
536901	Month 6	SP17	0.244	15.5	POSITIVE	ConfP-17	99.7	YES	TP233	3.7
536901	Month 9	SP18	0.202	11.8	POSITIVE	ConfP-17	98.0	YES	TP233	3.7
536901	Month 12	SP18	0.340	22.3	POSITIVE	ConfP-17	99.7	YES	TP233	3.7
536901	Month 18	SP18	0.390	26.1	POSITIVE	ConfP-17	100.0	YES	TP233	3.7
536901	Month 24	SP18	0.325	21.2	POSITIVE	ConfP-17	99.5	YES	TP233	3.7
536902	Baseline	SP18	0.049	0.2	Negative					
536902	Month 1	SP18	0.939	67.8	POSITIVE	ConfP-17	99.6	YES	TP234	3.7
536902	Month 3	SP18	1.248	91.3	POSITIVE	ConfP-2	100.0	YES	TP9	3.7
536902	Month 6	SP18	0.633	44.6	POSITIVE	ConfP-17	99.4	YES	TP234	3.7
536902	Month 9	SP18	0.987	71.5	POSITIVE	ConfP-17	99.8	YES	TP234	3.7
536902	Month 12	SP18	0.341	22.4	POSITIVE	ConfP-17	99.0	YES	TP234	3.7
536902	Month 18	SP18	0.292	18.7	POSITIVE	ConfP-17	98.2	YES	TP234	3.7
536902	Month 24	SP18	0.194	11.2	POSITIVE	ConfP-18R	98.4	YES	TP234	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536905	Baseline	SP103	0.048	0.5	Negative					
536905	Month 1	SP103	0.136	7.5	POSITIVE	ConfP-77	95.6	YES	TP96	2.7
536905	Month 3	SP103	0.185	11.4	POSITIVE	ConfP-77	97.2	YES	TP96	2.7
536905	Month 6	SP103	0.077	2.8	POSITIVE	ConfP-78	94.4	YES	TP96	2.7
536905	Month 9	SP103	0.083	3.3	POSITIVE	ConfP-78	88.2	YES	TP96	2.7
536905	Month 12	SP103	0.075	2.6	POSITIVE	ConfP-78	95.8	YES	TP96	2.7
536905	Month 18	SP103	0.066	1.9	POSITIVE	ConfP-78	90.9	YES	TP96	2.7
536905	Month 24	SP103	0.060	1.4	Negative					
536906	Baseline	SP97	0.058	1.2	Negative					
536906	Month 1	SP97	0.260	14.8	POSITIVE	ConfP-73	99.5	YES	TP86	2.7
536906	Month 3	SP97	0.431	26.4	POSITIVE	ConfP-73	99.2	YES	TP86	3.7
536906	Month 6	SP97	0.814	52.4	POSITIVE	ConfP-73	98.6	YES	TP86	3.7
536906	Month 9	SP97	0.474	29.3	POSITIVE	ConfP-73	98.6	YES	TP86	3.7
536906	Month 12	SP97	0.243	13.7	POSITIVE	ConfP-73	98.3	YES	TP86	2.7
536906	Month 18	SP97	0.161	8.1	POSITIVE	ConfP-73	98.3	YES	TP87	2.7
536906	Month 24	SP97	0.175	9.1	POSITIVE	ConfP-73	98.5	YES	TP87	2.7
536909	Baseline	SP97	0.045	0.3	Negative					
536909	Month 1	SP97	0.107	4.5	POSITIVE	ConfP-73	93.4	YES	TP87	2.7
536909	Month 3	SP97	0.319	18.8	POSITIVE	ConfP-73	97.7	YES	TP87	3.7
536909	Month 6	SP97	0.163	8.3	POSITIVE	ConfP-74	95.7	YES	TP87	2.7
536909	Month 9	SP98	0.191	8.6	POSITIVE	ConfP-74	95.3	YES	TP89	2.7
536909	Month 12	SP98	0.185	8.3	POSITIVE	ConfP-74	97.4	YES	TP89	2.7
536909	Month 18	SP98	0.120	4.4	POSITIVE	ConfP-74	94.9	YES	TP89	2.7
536909	Month 24	SP98	0.101	3.3	POSITIVE	ConfP-74	94.2	YES	TP89	2.7
536912	Baseline	SP98	0.046	0.1	Negative					
536912	Month 1	SP98	0.079	2.0	POSITIVE	ConfP-74	100.0	YES	TP87	2.7
536912	Month 3	SP98	0.721	40.0	POSITIVE	ConfP-74	99.9	YES	TP88	3.7
536912	Month 6	SP98	0.334	17.1	POSITIVE	ConfP-74	100.0	YES	TP88	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
536912	Month 9	SP98	0.327	16.7	POSITIVE	ConfP-74	100.0	YES	TP88	2.7
536912	Month 12	SP98	0.217	10.2	POSITIVE	ConfP-74	100.0	YES	TP88	2.7
536912	Month 18	SP98	0.248	12.0	POSITIVE	ConfP-74	100.0	YES	TP88	2.7
536912	Month 24	SP98	0.718	39.8	POSITIVE	ConfP-74	100.0	YES	TP88	3.7
536913	Baseline	SP92	0.048	0.2	Negative					
536913	Month 1	SP92	0.988	51.7	POSITIVE	ConfP-69	99.6	YES	TP78	3.7
536913	Month 3	SP92	1.847	98.8	POSITIVE	ConfP-69	98.6	YES	TP78	4.7
536913	Month 6	SP92	1.645	87.7	POSITIVE	ConfP-69	98.9	YES	TP78	4.7
536913	Month 9	SP92	1.668	89.0	POSITIVE	ConfP-69	99.5	YES	TP78	3.7
536913	Month 12	SP92	1.062	55.8	POSITIVE	ConfP-69	99.4	YES	TP78	3.7
536913	Month 18	SP92	0.864	44.9	POSITIVE	ConfP-69	99.5	YES	TP78	3.7
536913	Month 24	SP92	1.012	53.0	POSITIVE	ConfP-70	99.7	YES	TP79	3.7
536914	Baseline	SP91	0.045	0.0	Negative					
536914	Month 1	SP91	0.905	45.3	POSITIVE	ConfP-69	99.6	YES	TP76	3.7
536914	Month 3	SP91	2.243	115.8	POSITIVE	ConfP-69	99.1	YES	TP77	4.7
536914	Month 6	SP91	0.979	49.2	POSITIVE	ConfP-69	99.4	YES	TP77	3.7
536914	Month 9	SP91	0.616	30.1	POSITIVE	ConfP-69	98.9	YES	TP77	3.7
536914	Month 12	SP91	0.512	24.6	POSITIVE	ConfP-69	96.5	YES	TP77	3.7
536914	Month 18	SP91	0.272	12.0	POSITIVE	ConfP-69	98.8	YES	TP77	3.7
536914	Month 24	SP91	0.114	3.6	POSITIVE	ConfP-69	96.1	YES	TP77	2.7
536916	Baseline	SP90	0.047	0.1	Negative					
536916	Month 1	SP90	0.074	1.5	POSITIVE	ConfP-68	94.1	YES	TP75	2.7
536916	Month 3	SP90	0.128	4.4	POSITIVE	ConfP-68	97.8	YES	TP75	2.7
536916	Month 6	SP90	0.097	2.8	POSITIVE	ConfP-68	97.3	YES	TP75	2.7
536916	Month 9	SP90	0.142	5.1	POSITIVE	ConfP-68	85.1	YES	TP75	2.7
536916	Month 12	SP90	0.067	1.2	Negative					
536916	Month 18	SP90	0.089	2.3	POSITIVE	ConfP-68	91.8	YES	TP75	2.7
536916	Month 24	SP90	0.455	21.7	POSITIVE	ConfP-68	98.2	YES	TP76	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537001	Baseline	SP89	0.067	1.4	Negative					
537001	Month 1	SP89	1.337	71.1	POSITIVE	ConfP-68	98.5	YES	TP74	3.7
537001	Month 3	SP89	2.025	108.9	POSITIVE	ConfP-68	99.2	YES	TP74	4.7
537001	Month 6	SP89	1.667	89.2	POSITIVE	ConfP-68	99.5	YES	TP75	4.7
537001	Month 9	SP90	1.401	71.8	POSITIVE	ConfP-68	99.1	YES	TP76	3.7
537001	Month 12	SP90	1.069	54.2	POSITIVE	ConfP-68	99.2	YES	TP76	3.7
537001	Month 18	SP90	1.504	77.2	POSITIVE	ConfP-68	99.4	YES	TP76	3.7
537001	Month 24	SP90	1.672	86.1	POSITIVE	ConfP-68	99.2	YES	TP76	3.7
537002	Baseline	SP89	0.044	0.1	Negative					
537002	Month 1	SP89	0.525	26.5	POSITIVE	ConfP-67	99.3	YES	TP73	2.7
537002	Month 3	SP89	0.875	45.7	POSITIVE	ConfP-67	99.5	YES	TP73	3.7
537002	Month 6	SP89	0.624	32.0	POSITIVE	ConfP-67	98.9	YES	TP73	3.7
537002	Month 9	SP89	0.510	25.7	POSITIVE	ConfP-67	99.4	YES	TP74	3.7
537002	Month 12	SP89	0.264	12.2	POSITIVE	ConfP-67	99.1	YES	TP74	2.7
537002	Month 18	SP89	0.315	15.0	POSITIVE	ConfP-67	99.1	YES	TP74	2.7
537002	Month 24	SP89	0.182	7.7	POSITIVE	ConfP-67	98.6	YES	TP74	2.7
537003	Baseline	SP93	0.044	0.1	Negative					
537003	Month 1	SP93	0.332	12.7	POSITIVE	ConfP-70	99.1	YES	TP79	3.7
537003	Month 3	SP93	1.936	83.1	POSITIVE	ConfP-70	99.0	YES	TP79	4.7
537003	Month 6	SP93	1.045	44.0	POSITIVE	ConfP-70	99.4	YES	TP79	3.7
537003	Month 9	SP93	0.184	6.2	POSITIVE	ConfP-70	98.3	YES	TP79	2.7
537003	Month 12	SP93	0.809	33.7	POSITIVE	ConfP-70	98.9	YES	TP79	3.7
537003	Month 18	SP93	0.285	10.7	POSITIVE	ConfP-70	98.6	YES	TP80	3.7
537003	Month 24	SP93	0.097	2.4	POSITIVE	ConfP-70	92.2	YES	TP80	2.7
537007	Baseline	SP93	0.044	0.1	Negative					
537007	Month 1	SP93	0.184	6.2	POSITIVE	ConfP-70	97.9	YES	TP80	3.7
537007	Month 3	SP93	1.188	50.3	POSITIVE	ConfP-70	98.7	YES	TP80	3.7
537007	Month 6	SP93	0.770	31.9	POSITIVE	ConfP-70	98.2	YES	TP80	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537007	Month 9	SP94	1.136	47.8	POSITIVE	ConfP-71	98.8	YES	TP82	3.7
537007	Month 12	SP94	0.849	35.3	POSITIVE	ConfP-71	97.8	YES	TP82	3.7
537007	Month 18	SP94	0.484	19.3	POSITIVE	ConfP-71	96.9	YES	TP82	3.7
537007	Month 24	SP94	0.263	9.7	POSITIVE	ConfP-71	97.1	YES	TP82	3.7
537008	Baseline	SP94	0.048	0.3	Negative					
537008	Month 1	SP94	0.596	24.2	POSITIVE	ConfP-70	94.8	YES	TP80	3.7
537008	Month 3	SP94	0.873	36.3	POSITIVE	ConfP-70	92.2	YES	TP81	3.7
537008	Month 6	SP94	0.682	28.0	POSITIVE	ConfP-71	96.2	YES	TP81	3.7
537008	Month 9	SP94	0.555	22.4	POSITIVE	ConfP-71	96.4	YES	TP81	3.7
537008	Month 12	SP94	0.344	13.2	POSITIVE	ConfP-71	94.6	YES	TP81	3.7
537008	Month 18	SP94	0.263	9.7	POSITIVE	ConfP-71	92.9	YES	TP81	3.7
537008	Month 24	SP94	0.418	16.4	POSITIVE	ConfP-71	93.0	YES	TP81	3.7
537010	Baseline	SP95	0.052	0.4	Negative					
537010	Month 1	SP95	1.681	68.3	POSITIVE	ConfP-71	99.5	YES	TP82	3.7
537010	Month 3	SP95	1.010	40.3	POSITIVE	ConfP-71	99.4	YES	TP82	3.7
537010	Month 6	SP95	0.323	11.7	POSITIVE	ConfP-71	98.0	YES	TP83	3.7
537010	Month 9	SP95	0.534	20.5	POSITIVE	ConfP-71	99.1	YES	TP83	3.7
537010	Month 12	SP95	0.690	27.0	POSITIVE	ConfP-72	99.2	YES	TP83	3.7
537010	Month 18	SP95	0.407	15.2	POSITIVE	ConfP-72	99.1	YES	TP83	3.7
537010	Month 24	SP95	0.370	13.6	POSITIVE	ConfP-72	99.3	YES	TP83	3.7
537012	Baseline	SP95	0.050	0.3	Negative					
537012	Month 1	SP95	0.099	2.3	POSITIVE	ConfP-72	96.9	YES	TP83	2.7
537012	Month 3	SP95	1.460	59.1	POSITIVE	ConfP-72	99.0	YES	TP84	3.7
537012	Month 6	SP95	0.528	20.2	POSITIVE	ConfP-72	98.3	YES	TP84	3.7
537012	Month 9	SP96	0.205	7.5	POSITIVE	ConfP-73	98.6	YES	TP85	2.7
537012	Month 12	SP96	0.210	7.7	POSITIVE	ConfP-73	99.0	YES	TP85	2.7
537012	Month 18	SP96	0.149	4.9	POSITIVE	ConfP-73	97.2	YES	TP85	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537012	Month 24	SP96	0.137	4.3	POSITIVE	ConfP-73	98.4	YES	TP86	2.7
537013	Baseline	SP96	0.047	0.1	Negative					
537013	Month 1	SP96	0.709	30.8	POSITIVE	ConfP-72	99.4	YES	TP84	3.7
537013	Month 3	SP96	0.596	25.6	POSITIVE	ConfP-72	98.9	YES	TP84	3.7
537013	Month 6	SP96	0.537	22.8	POSITIVE	ConfP-72	98.9	YES	TP84	3.7
537013	Month 9	SP96	0.363	14.8	POSITIVE	ConfP-72	98.7	YES	TP84	3.7
537013	Month 12	SP96	0.185	6.5	POSITIVE	ConfP-72	98.7	YES	TP85	2.7
537013	Month 18	SP96	0.113	3.2	POSITIVE	ConfP-72	95.5	YES	TP85	2.7
537013	Month 24	SP96	0.125	3.8	POSITIVE	ConfP-72	94.0	YES	TP85	2.7
537015	Baseline	SP99	0.044	0.0	Negative					
537015	Month 1	SP99	1.349	73.5	POSITIVE	ConfP-74	88.1	YES	TP89	3.7
537015	Month 3	SP99	1.439	78.6	POSITIVE	ConfP-75	99.3	YES	TP89	3.7
537015	Month 6	SP99	0.485	24.7	POSITIVE	ConfP-75	99.4	YES	TP90	3.7
537015	Month 9	SP99	0.694	36.5	POSITIVE	ConfP-75	99.5	YES	TP90	3.7
537015	Month 12	SP99	0.354	17.3	POSITIVE	ConfP-75	99.2	YES	TP90	2.7
537015	Month 18	SP99	0.373	18.4	POSITIVE	ConfP-75	99.4	YES	TP90	2.7
537015	Month 24	SP99	0.077	1.6	POSITIVE	ConfP-75	94.9	YES	TP90	2.7
537101	Baseline	SP188	0.095	0.0	Negative					
537101	Month 1	SP188	0.171	3.3	POSITIVE	ConfP-140	97.4	YES	TP299	2.7
537101	Month 3					No sample received				
537101	Month 6	SP199	1.170	60.8	POSITIVE	ConfP-140	99.2	YES	TP299	3.7
537101	Month 9	SP199	0.667	32.7	POSITIVE	ConfP-140	98.7	YES	TP299	2.7
537101	Month 12	SP188	0.633	24.1	POSITIVE	ConfP-140	98.4	YES	TP299	2.7
537101	Month 18	SP188	0.548	20.3	POSITIVE	ConfP-140	98.6	YES	TP299	2.7
537101	Month 24	SP196	0.910	35.1	POSITIVE	ConfP-140	98.1	YES	TP299	2.7
537102	Baseline	SP189	0.094	1.3	Negative					
537102	Month 1	SP189	0.791	32.7	POSITIVE	ConfP-134	100.0	YES	TP291	3.7
537102	Month 3					No sample received				

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537102	Month 6	SP189	0.912	38.2	POSITIVE	ConfP-134	99.6	YES	TP291	2.7
537102	Month 9	SP189	0.293	10.2	POSITIVE	ConfP-134	100.0	YES	TP317	2.7
537102	Month 12	SP189	0.435	16.6	POSITIVE	ConfP-134	100.0	YES	TP314	2.7
537102	Month 18	SP189	0.760	31.3	POSITIVE	ConfP-134	100.0	YES	TP314	2.7
537102	Month 24	SP196	1.055	41.1	POSITIVE	ConfP-134	99.7	YES	TP314	2.7
537106	Baseline	SP189	0.077	0.5	Negative					
537106	Month 1	SP189	1.621	70.1	POSITIVE	ConfP-134	99.9	YES	TP314	3.7
537106	Month 3					No sample received				
537106	Month 6	SP189	2.539	111.5	POSITIVE	ConfP-134	99.4	YES	TP292	3.7
537106	Month 9	SP189	2.453	107.7	POSITIVE	ConfP-134	99.6	YES	TP292	4.7
537106	Month 12	SP189	2.449	107.5	POSITIVE	ConfP-134	99.6	YES	TP292	3.7
537106	Month 18	SP189	2.239	98.0	POSITIVE	ConfP-134	99.6	YES	TP292	3.7
537106	Month 24	SP189	2.020	88.1	POSITIVE	ConfP-134	99.6	YES	TP292	3.7
537109	Baseline	SP19	0.043	0.0	Negative					
537109	Month 1	SP19	0.199	12.0	POSITIVE	ConfP-18R	99.5	YES	TP235	2.7
537109	Month 3	SP19	0.548	41.2	POSITIVE	ConfP-2	100.0	YES	TP9	3.7
537109	Month 6	SP19	0.484	35.9	POSITIVE	ConfP-18R	99.6	YES	TP235	3.7
537109	Month 9	SP19	0.238	15.3	POSITIVE	ConfP-18R	99.6	YES	TP235	2.7
537109	Month 12	SP19	0.168	9.4	POSITIVE	ConfP-18R	99.3	YES	TP235	2.7
537109	Month 18	SP19	0.146	7.6	POSITIVE	ConfP-18R	99.2	YES	TP235	2.7
537109	Month 24	SP19	0.224	14.1	POSITIVE	ConfP-18R	99.5	YES	TP235	2.7
537111	Baseline	SP19	0.044	0.0	Negative					
537111	Month 1	SP19	0.147	7.7	POSITIVE	ConfP-18R	99.0	YES	TP236	2.7
537111	Month 3	SP19	0.393	28.3	POSITIVE	ConfP-3	100.0	YES	TP9	2.7
537111	Month 6	SP19	0.104	4.1	POSITIVE	ConfP-18R	98.0	YES	TP236	2.7
537111	Month 9	SP20	0.085	3.3	POSITIVE	ConfP-18R	98.0	YES	TP236	2.7
537111	Month 12	SP20	0.060	1.2	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537111	Month 18	SP20	0.066	1.7	POSITIVE	ConfP-18R	97.8	YES	TP236	2.7
537111	Month 24	SP20	0.070	2.1	POSITIVE	ConfP-18R	97.5	YES	TP236	2.7
537113	Baseline	Whole blood sample received instead of serum, not analysed.								
537113	Month 1	No sample received								
537113	Month 3	SP185	0.780	34.7	POSITIVE	ConfP-137	99.1	YES	TP296	3.7
537113	Month 6	SP185	0.240	8.2	POSITIVE	ConfP-137	97.3	YES	TP296	2.7
537113	Month 9	SP185	0.166	4.6	POSITIVE	ConfP-137	96.9	YES	TP296	2.7
537113	Month 12	SP185	0.253	8.9	POSITIVE	ConfP-137	98.7	YES	TP296	2.7
537113	Month 18	SP185	0.176	5.1	POSITIVE	ConfP-137	96.0	YES	TP296	2.7
537113	Month 24	SP185	0.342	13.2	POSITIVE	ConfP-137	99.3	YES	TP296	2.7
537114	Baseline	SP20	0.062	1.4	Negative					
537114	Month 1	SP20	0.640	50.9	POSITIVE	ConfP-18R	98.3	YES	TP236	3.7
537114	Month 3	SP20	1.359	112.6	POSITIVE	ConfP-3	99.4	YES	TP9	3.7
537114	Month 6	SP20	1.129	92.9	POSITIVE	ConfP-19R	98.6	YES	TP237	3.7
537114	Month 9	SP20	0.299	21.7	POSITIVE	ConfP-19R	98.1	YES	TP237	2.7
537114	Month 12	SP20	1.024	83.9	POSITIVE	ConfP-19R	98.6	YES	TP237	3.7
537114	Month 18	SP20	0.830	67.2	POSITIVE	ConfP-19R	98.2	YES	TP237	3.7
537114	Month 24	SP20	0.757	61.0	POSITIVE	ConfP-19R	97.0	YES	TP237	3.7
537116	Baseline	SP21	0.045	0.1	Negative					
537116	Month 1	SP21	0.059	1.0	Negative					
537116	Month 3	SP21	0.748	44.9	POSITIVE	ConfP-3	99.3	YES	TP9	3.7
537116	Month 6	SP21	0.571	33.6	POSITIVE	ConfP-19R	99.5	YES	TP237	3.7
537116	Month 9	SP21	0.378	21.3	POSITIVE	ConfP-19R	99.4	YES	TP238	3.7
537116	Month 12	SP21	0.321	17.7	POSITIVE	ConfP-19R	99.4	YES	TP238	2.7
537116	Month 18	SP21	0.466	26.9	POSITIVE	ConfP-19R	99.4	YES	TP238	3.7
537116	Month 24	SP21	0.339	18.9	POSITIVE	ConfP-19R	99.2	YES	TP238	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537117	Baseline	SP21	0.045	0.1	Negative					
537117	Month 1	SP21	0.407	23.2	POSITIVE	ConfP-19R	99.1	YES	TP238	3.7
537117	Month 3	SP21	0.761	45.7	POSITIVE	ConfP-3	100.0	YES	TP9	3.7
537117	Month 6	SP21	0.493	28.7	POSITIVE	ConfP-19R	99.0	YES	TP238	3.7
537117	Month 9	SP22	0.219	12.7	POSITIVE	ConfP-19R	96.7	YES	TP239	2.7
537117	Month 12	SP22	0.131	6.3	POSITIVE	ConfP-20R	97.4	YES	TP239	2.7
537117	Month 18	SP22	0.108	4.6	POSITIVE	ConfP-20R	96.1	YES	TP239	2.7
537117	Month 24	SP22	0.076	2.3	POSITIVE	ConfP-20R	93.7	YES	TP239	2.7
537118	Baseline	SP22	0.046	0.1	Negative					
537118	Month 1	SP22	0.135	6.6	POSITIVE	ConfP-20R	97.9	YES	TP239	2.7
537118	Month 3	SP22	1.355	95.6	POSITIVE	ConfP-3	100.0	YES	TP10	3.7
537118	Month 6	SP22	0.252	15.1	POSITIVE	ConfP-20R	99.5	YES	TP239	2.7
537118	Month 9	SP22	0.409	26.5	POSITIVE	ConfP-20R	99.2	YES	TP240	3.7
537118	Month 12	SP22	0.590	39.8	POSITIVE	ConfP-20R	99.6	YES	TP240	3.7
537118	Month 18	SP22	0.146	7.4	POSITIVE	ConfP-20R	98.5	YES	TP240	2.7
537118	Month 24	SP22	0.196	11.0	POSITIVE	ConfP-20R	99.2	YES	TP240	2.7
537121	Baseline	SP99	0.047	0.0	Negative					
537121	Month 1	SP99	0.074	1.5	POSITIVE	ConfP-75	100.0	YES	TP90	2.7
537121	Month 3	SP99	1.878	103.4	POSITIVE	ConfP-75	97.7	YES	TP91R	4.7
537121	Month 6	SP99	0.922	49.4	POSITIVE	ConfP-75	99.6	YES	TP91R	3.7
537121	Month 9	SP100	0.373	19.3	POSITIVE	ConfP-76	98.9	YES	TP92	3.7
537121	Month 12	SP100	0.317	16.1	POSITIVE	ConfP-76	98.9	YES	TP92	3.7
537121	Month 18	SP100	0.055	0.8	Negative					
537121	Month 24	SP100	0.367	19.0	POSITIVE	ConfP-76	99.0	YES	TP92	3.7
537123	Baseline	SP100	0.049	0.4	Negative					
537123	Month 1	SP100	0.222	10.5	POSITIVE	ConfP-75	98.7	YES	TP91R	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537123	Month 3	SP100	0.203	9.4	POSITIVE	ConfP-75	98.3	YES	TP91R	2.7
537123	Month 6	SP100	0.111	4.0	POSITIVE	ConfP-75	96.7	YES	TP91R	2.7
537123	Month 9	SP100	0.079	2.2	POSITIVE	ConfP-75	89.7	YES	TP91R	2.7
537123	Month 12	SP100	0.073	1.8	POSITIVE	ConfP-76	88.0	YES	TP92	2.7
537123	Month 18	SP100	0.064	1.3	Negative					
537123	Month 24	SP100	0.052	0.6	Negative					
537125	Baseline	SP105R	0.044	0.1	Negative					
537125	Month 1	SP105R	1.517	95.7	POSITIVE	ConfP-79	99.4	YES	TP99	3.7
537125	Month 3	SP105R	1.239	77.7	POSITIVE	ConfP-79	99.5	YES	TP99	3.7
537125	Month 6	SP105R	0.411	23.9	POSITIVE	ConfP-79	99.3	YES	TP99	2.7
537125	Month 9	SP105R	0.264	14.4	POSITIVE	ConfP-79	97.6	YES	TP99	2.7
537125	Month 12	SP105R	0.332	18.8	POSITIVE	ConfP-79	99.0	YES	TP99	2.7
537125	Month 18	SP105R	0.307	17.2	POSITIVE	ConfP-79	99.6	YES	TP100	2.7
537125	Month 24	SP105R	0.349	19.9	POSITIVE	ConfP-79	99.4	YES	TP100	2.7
537130	Baseline	SP195	0.141	3.2	POSITIVE	ConfP-147	65.5	YES	TP315	<2.7
537130	Month 1	SP195	1.135	43.0	POSITIVE	ConfP-144	99.2	YES	TP300	2.7
537130	Month 3	SP195	2.284	89.0	POSITIVE	ConfP-144	99.7	YES	TP300	3.7
537130	Month 6	SP195	2.029	78.7	POSITIVE	ConfP-144	99.6	YES	TP300	3.7
537130	Month 9	SP195	1.133	42.9	POSITIVE	ConfP-144	98.6	YES	TP300	2.7
537130	Month 12					No sample received				
537130	Month 18	SP195	1.288	49.1	POSITIVE	ConfP-144	99.3	YES	TP300	2.7
537130	Month 24	SP195	0.944	35.3	POSITIVE	ConfP-144	99.2	YES	TP300	2.7
537131	Baseline	SP195	0.071	0.4	Negative					
537131	Month 1	SP195	0.538	19.1	POSITIVE	ConfP-144	98.9	YES	TP301	2.7
537131	Month 3	SP195	0.877	32.6	POSITIVE	ConfP-144	99.7	YES	TP301	2.7
537131	Month 6	SP195	0.432	14.8	POSITIVE	ConfP-144	98.6	YES	TP301	2.7
537131	Month 9	SP195	0.194	5.3	POSITIVE	ConfP-144	97.3	YES	TP301	2.7
537131	Month 12					No sample received				

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537131	Month 18	SP195	0.247	7.4	POSITIVE	ConfP-144	98.7	YES	TP301	2.7
537131	Month 24	SP196	0.290	9.5	POSITIVE	ConfP-144	97.9	YES	TP301	2.7
537132	Baseline	SP105R	0.045	0.2	Negative					
537132	Month 1	SP105R	0.057	1.0	Negative					
537132	Month 3	SP105R	0.457	26.9	POSITIVE	ConfP-79	98.3	YES	TP100	2.7
537132	Month 6	SP105R	0.379	21.9	POSITIVE	ConfP-79	98.8	YES	TP100	2.7
537132	Month 9	SP106R	0.387	20.2	POSITIVE	ConfP-80	98.4	YES	TP101	2.7
537132	Month 12	SP106R	0.483	25.9	POSITIVE	ConfP-80	98.0	YES	TP102	3.7
537132	Month 18	SP106R	0.143	6.0	POSITIVE	ConfP-80	96.6	YES	TP102	2.7
537132	Month 24	SP106R	0.223	10.6	POSITIVE	ConfP-80	96.8	YES	TP102	2.7
537201	Baseline	SP23	0.044	0.1	Negative					
537201	Month 1	SP23	1.830	113.8	POSITIVE	ConfP-20R	99.4	YES	TP240	3.7
537201	Month 3	SP23	1.973	122.9	POSITIVE	ConfP-3	99.7	YES	TP10	3.7
537201	Month 6	SP23	1.481	91.6	POSITIVE	ConfP-20R	99.2	YES	TP240	3.7
537201	Month 9	SP23	1.199	73.6	POSITIVE	ConfP-20R	99.4	YES	TP241	3.7
537201	Month 12	SP23	1.180	72.4	POSITIVE	ConfP-20R	99.6	YES	TP241	3.7
537201	Month 18	SP23	1.507	93.2	POSITIVE	ConfP-21	99.1	YES	TP241	3.7
537201	Month 24	SP23	1.808	112.4	POSITIVE	ConfP-21	99.5	YES	TP241	3.7
537203	Baseline	SP23	0.051	0.5	Negative					
537203	Month 1	SP23	0.148	6.7	POSITIVE	ConfP-21	92.5	YES	TP241	2.7
537203	Month 3	SP23	1.483	91.7	POSITIVE	ConfP-3	99.4	YES	TP10	3.7
537203	Month 6	SP23	1.339	82.5	POSITIVE	ConfP-21	98.8	YES	TP241	3.7
537203	Month 9	SP24	1.026	73.2	POSITIVE	ConfP-21	99.2	YES	TP242	3.7
537203	Month 12	SP24	0.921	65.3	POSITIVE	ConfP-21	99.3	YES	TP242	3.7
537203	Month 18	SP24	0.677	47.1	POSITIVE	ConfP-21	98.5	YES	TP242	3.7
537203	Month 24	SP24	0.604	41.6	POSITIVE	ConfP-21	98.1	YES	TP242	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537205	Baseline	SP106R	0.047	0.4	Negative					
537205	Month 1	SP106R	1.973	113.0	POSITIVE	ConfP-80	97.0	YES	TP100	3.7
537205	Month 3	SP106R	2.510	144.5	POSITIVE	ConfP-80	96.1	YES	TP100	4.7
537205	Month 6	SP106R	2.366	136.0	POSITIVE	ConfP-80	98.5	YES	TP101	4.7
537205	Month 9	SP106R	2.200	126.3	POSITIVE	ConfP-80	98.1	YES	TP101	3.7
537205	Month 12	SP106R	2.263	130.0	POSITIVE	ConfP-80	98.6	YES	TP101	4.7
537205	Month 18	SP106R	1.786	102.1	POSITIVE	ConfP-80	99.1	YES	TP101	3.7
537205	Month 24	SP106R	1.479	84.1	POSITIVE	ConfP-80	99.0	YES	TP101	3.7
537206	Baseline	SP107R	0.047	0.4	Negative					
537206	Month 1	SP107R	0.070	2.4	POSITIVE	ConfP-80	84.0	YES	TP102	<2.7
537206	Month 3	SP107R	0.411	31.7	POSITIVE	ConfP-80	98.8	YES	TP102	2.7
537206	Month 6	SP107R	0.554	43.9	POSITIVE	ConfP-81	99.3	YES	TP102	2.7
537206	Month 9	SP107R	0.366	27.8	POSITIVE	ConfP-81	99.5	YES	TP103	2.7
537206	Month 12	SP107R	0.408	31.4	POSITIVE	ConfP-81	99.2	YES	TP103	2.7
537206	Month 18	SP107R	0.312	23.2	POSITIVE	ConfP-81	98.6	YES	TP103	2.7
537206	Month 24	SP107R	0.189	12.6	POSITIVE	ConfP-81	97.8	YES	TP103	2.7
537207	Baseline	SP107R	0.048	0.5	Negative					
537207	Month 1	SP107R	0.266	19.2	POSITIVE	ConfP-81	98.5	YES	TP103	2.7
537207	Month 3	SP107R	0.448	34.8	POSITIVE	ConfP-81	99.4	YES	TP103	3.7
537207	Month 6	SP107R	0.485	38.0	POSITIVE	ConfP-81	99.4	YES	TP104	3.7
537207	Month 9	SP108R	0.490	32.5	POSITIVE	ConfP-82R	99.1	YES	TP105	2.7
537207	Month 12	SP108R	0.475	31.4	POSITIVE	ConfP-82R	99.0	YES	TP105	3.7
537207	Month 18	SP108R	0.348	22.2	POSITIVE	ConfP-82R	99.1	YES	TP105	2.7
537207	Month 24	SP108R	0.154	8.1	POSITIVE	ConfP-82R	97.5	YES	TP105	2.7
537208	Baseline	SP108R	0.057	1.1	Negative					
537208	Month 1	SP108R	0.818	56.3	POSITIVE	ConfP-81	98.9	YES	TP104	3.7
537208	Month 3	SP108R	1.616	114.1	POSITIVE	ConfP-81	99.5	YES	TP104	3.7
537208	Month 6	SP108R	0.256	15.5	POSITIVE	ConfP-81	98.6	YES	TP104	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537208	Month 9	SP108R	1.523	107.4	POSITIVE	ConfP-81	99.4	YES	TP104	3.7
537208	Month 12	SP108R	0.520	34.7	POSITIVE	ConfP-81	99.0	YES	TP104	3.7
537208	Month 18	SP108R	0.259	15.7	POSITIVE	ConfP-82R	97.8	YES	TP105	2.7
537208	Month 24	SP108R	0.566	38.0	POSITIVE	ConfP-82R	98.7	YES	TP105	3.7
537210	Baseline	SP109R	0.046	0.2	Negative					
537210	Month 1	SP109R	0.104	4.1	POSITIVE	ConfP-82R	98.0	YES	TP106	2.7
537210	Month 3	SP109R	1.557	100.6	POSITIVE	ConfP-82R	99.4	YES	TP106	3.7
537210	Month 6	SP109R	0.988	62.8	POSITIVE	ConfP-82R	99.3	YES	TP106	3.7
537210	Month 9	SP109R	0.727	45.4	POSITIVE	ConfP-82R	99.6	YES	TP106	3.7
537210	Month 12	SP109R	0.639	39.6	POSITIVE	ConfP-82R	99.4	YES	TP106	3.7
537210	Month 18	SP109R	0.336	19.5	POSITIVE	ConfP-82R	99.2	YES	TP106	2.7
537210	Month 24	SP109R	0.340	19.7	POSITIVE	ConfP-82R	98.8	YES	TP107	3.7
537214	Baseline	SP109R	0.044	0.1	Negative					
537214	Month 1	SP109R	0.044	0.1	Negative					
537214	Month 3	SP109R	0.112	4.6	POSITIVE	ConfP-83R	97.5	YES	TP107	2.7
537214	Month 6	SP109R	0.152	7.2	POSITIVE	ConfP-83R	98.7	YES	TP107	2.7
537214	Month 9	SP110	0.064	1.0	Negative					
537214	Month 12	SP110	0.054	0.6	Negative					
537214	Month 18	SP110	0.084	1.8	POSITIVE	ConfP-83R	96.4	YES	TP108	2.7
537214	Month 24	SP110	0.070	1.2	Negative					
537215	Baseline	SP110	0.057	0.7	Negative					
537215	Month 1	SP110	1.955	82.1	POSITIVE	ConfP-83R	97.0	YES	TP107	3.7
537215	Month 3	SP110	1.347	56.0	POSITIVE	ConfP-83R	93.3	YES	TP107	3.7
537215	Month 6	SP110	1.054	43.5	POSITIVE	ConfP-83R	91.9	YES	TP107	3.7
537215	Month 9	SP110	1.834	76.9	POSITIVE	ConfP-83R	95.6	YES	TP108	4.7
537215	Month 12	SP110	1.834	76.9	POSITIVE	ConfP-83R	97.4	YES	TP108	4.7
537215	Month 18	SP110	1.579	66.0	POSITIVE	ConfP-83R	97.2	YES	TP108	3.7
537215	Month 24	SP110	1.257	52.2	POSITIVE	ConfP-83R	97.6	YES	TP108	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537216	Baseline	SP111	0.068	1.2	Negative					
537216	Month 1	SP111	0.073	1.4	Negative					
537216	Month 3	SP111	0.883	39.9	POSITIVE	ConfP-83R	99.0	YES	TP108	3.7
537216	Month 6	SP111	0.510	22.2	POSITIVE	ConfP-83R	98.2	YES	TP109	3.7
537216	Month 9	SP111	0.167	5.9	POSITIVE	ConfP-83R	95.7	YES	TP109	2.7
537216	Month 12	SP111	0.113	3.3	POSITIVE	ConfP-84	94.2	YES	TP109	2.7
537216	Month 18	SP111	0.121	3.7	POSITIVE	ConfP-84	96.4	YES	TP109	2.7
537216	Month 24	SP111	0.167	5.9	POSITIVE	ConfP-84	97.7	YES	TP109	2.7
537305	Baseline	SP24	0.047	0.0	Negative					
537305	Month 1	SP24	0.509	34.5	POSITIVE	ConfP-21	98.3	YES	TP242	3.7
537305	Month 3	SP24	1.644	119.5	POSITIVE	ConfP-3	99.5	YES	TP10	3.7
537305	Month 6	SP24	0.526	35.8	POSITIVE	ConfP-21	95.5	YES	TP242	3.7
537305	Month 9	SP24	0.431	28.7	POSITIVE	ConfP-21	97.5	YES	TP243	2.7
537305	Month 12	SP24	0.196	11.1	POSITIVE	ConfP-21	97.0	YES	TP243	2.7
537305	Month 18	SP24	0.201	11.5	POSITIVE	ConfP-21	93.8	YES	TP243	2.7
537305	Month 24	SP24	0.123	5.6	POSITIVE	ConfP-22	93.2	YES	TP243	2.7
537307	Baseline	SP25	0.046	0.2	Negative					
537307	Month 1	SP25	2.628	129.4	POSITIVE	ConfP-22	93.5	YES	TP243	4.7
537307	Month 3	SP25	2.636	129.8	POSITIVE	ConfP-3	98.1	YES	TP10	3.7
537307	Month 6	SP25	2.355	115.7	POSITIVE	ConfP-22	96.8	YES	TP243	3.7
537307	Month 9	SP25	2.035	99.7	POSITIVE	ConfP-22	97.2	YES	TP244	3.7
537307	Month 12	SP25	1.690	82.4	POSITIVE	ConfP-22	95.8	YES	TP244	3.7
537307	Month 18	SP25	1.381	67.0	POSITIVE	ConfP-22	93.8	YES	TP244	3.7
537307	Month 24	SP25	1.594	77.6	POSITIVE	ConfP-22	86.1	YES	TP244	3.7
537309	Baseline	SP25	0.044	0.1	Negative					
537309	Month 1	SP25	2.075	101.7	POSITIVE	ConfP-22	99.5	YES	TP244	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537309	Month 3	SP25	2.411	118.5	POSITIVE	ConfP-3	99.7	YES	TP10	3.7
537309	Month 6	SP25	1.527	74.3	POSITIVE	ConfP-22	99.2	YES	TP244	3.7
537309	Month 9	SP26	1.548	76.7	POSITIVE	ConfP-22	99.4	YES	TP245	3.7
537309	Month 12	SP26	1.607	79.7	POSITIVE	ConfP-22	99.7	YES	TP245	3.7
537309	Month 18	SP26	0.918	44.5	POSITIVE	ConfP-22	99.3	YES	TP245	3.7
537309	Month 24	SP26	0.788	37.8	POSITIVE	ConfP-22	98.8	YES	TP245	3.7
537310	Baseline	SP26	0.052	0.2	Negative					
537310	Month 1	SP26	0.656	31.1	POSITIVE	ConfP-23	99.3	YES	TP245	2.7
537310	Month 3	SP26	1.685	83.7	POSITIVE	ConfP-3	99.8	YES	TP11	3.7
537310	Month 6	SP26	1.569	77.8	POSITIVE	ConfP-23	99.6	YES	TP245	3.7
537310	Month 9	SP26	0.619	29.2	POSITIVE	ConfP-23	99.3	YES	TP246	3.7
537310	Month 12	SP26	1.021	49.7	POSITIVE	ConfP-23	99.6	YES	TP246	3.7
537310	Month 18	SP26	1.475	73.0	POSITIVE	ConfP-23	99.7	YES	TP246	3.7
537310	Month 24	SP26	0.331	14.5	POSITIVE	ConfP-23	98.6	YES	TP246	2.7
537312	Baseline	SP27	0.044	0.0	Negative					
537312	Month 1	SP27	0.873	40.7	POSITIVE	ConfP-23	95.9	YES	TP246	3.7
537312	Month 3	SP27	2.052	98.4	POSITIVE	ConfP-23	98.1	YES	TP246	3.7
537312	Month 6	SP27	2.463	118.6	POSITIVE	ConfP-3	99.7	YES	TP11	3.7
537312	Month 9	SP27	2.174	104.4	POSITIVE	ConfP-23	98.9	YES	TP247	3.7
537312	Month 12	SP27	1.963	94.1	POSITIVE	ConfP-23	98.7	YES	TP247	3.7
537312	Month 18	SP27	1.743	83.3	POSITIVE	ConfP-23	98.7	YES	TP247	3.7
537312	Month 24	SP27	1.395	66.2	POSITIVE	ConfP-23	97.6	YES	TP247	3.7
537313	Baseline	SP111	0.067	1.1	Negative					
537313	Month 1	SP111	0.148	5.0	POSITIVE	ConfP-84	99.2	YES	TP109	2.7
537313	Month 3	SP111	0.682	30.4	POSITIVE	ConfP-84	99.5	YES	TP110	3.7
537313	Month 6	SP111	0.321	13.2	POSITIVE	ConfP-84	99.3	YES	TP110	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537313	Month 9	SP112	0.172	7.7	POSITIVE	ConfP-85	98.2	YES	TP111	3.7
537313	Month 12	SP112	0.101	3.5	POSITIVE	ConfP-85	98.1	YES	TP111	2.7
537313	Month 18	SP112	0.080	2.3	POSITIVE	ConfP-85	93.3	YES	TP111	2.7
537313	Month 24	SP112	0.073	1.8	POSITIVE	ConfP-85	93.4	YES	TP112	2.7
537315	Baseline	SP112	0.063	1.2	Negative					
537315	Month 1	SP112	0.300	15.3	POSITIVE	ConfP-84	99.4	YES	TP110	3.7
537315	Month 3	SP112	0.387	20.4	POSITIVE	ConfP-84	99.4	YES	TP110	3.7
537315	Month 6	SP112	0.104	3.7	POSITIVE	ConfP-84	99.0	YES	TP110	2.7
537315	Month 9	SP112	0.093	3.0	POSITIVE	ConfP-84	98.9	YES	TP110	2.7
537315	Month 12	SP112	0.101	3.5	POSITIVE	ConfP-84	98.1	YES	TP111	2.7
537315	Month 18	SP112	0.105	3.7	POSITIVE	ConfP-84	98.8	YES	TP111	2.7
537315	Month 24	SP112	0.111	4.1	POSITIVE	ConfP-84	98.3	YES	TP111	2.7
537316	Baseline	SP113R	0.049	0.0	Negative					
537316	Month 1	SP113R	0.079	1.4	Negative					
537316	Month 3	SP113R	0.518	26.7	POSITIVE	ConfP-85	98.4	YES	TP112	3.7
537316	Month 6	SP113R	0.385	19.1	POSITIVE	ConfP-85	98.6	YES	TP112	3.7
537316	Month 9	SP113R	0.118	3.6	POSITIVE	ConfP-85	96.1	YES	TP112	2.7
537316	Month 12	SP113R	0.155	5.8	POSITIVE	ConfP-85	97.0	YES	TP112	2.7
537316	Month 18	SP113R	0.256	11.6	POSITIVE	ConfP-85	98.1	YES	TP112	2.7
537316	Month 24	SP113R	0.101	2.7	POSITIVE	ConfP-85	96.4	YES	TP113	2.7
537317	Baseline	SP113R	0.053	0.0	Negative					
537317	Month 1	SP113R	0.091	2.1	POSITIVE	ConfP-85	18.7	No		
537317	Month 3	SP113R	0.353	17.2	POSITIVE	ConfP-85	47.0	No		
537317	Month 6	SP113R	0.275	12.7	POSITIVE	ConfP-85	99.6	YES	TP113	2.7
537317	Month 9	SP114R	0.280	13.4	POSITIVE	ConfP-86	80.6	YES	TP114	2.7
537317	Month 12	SP114R	0.196	8.7	POSITIVE	ConfP-86	85.9	YES	TP115	2.7
537317	Month 18	SP114R	0.201	8.9	POSITIVE	ConfP-86	88.5	YES	TP115	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537317	Month 24	SP114R	0.386	19.4	POSITIVE	ConfP-86	89.2	YES	TP115	3.7
537319	Baseline	SP114R	0.045	0.2	Negative					
537319	Month 1	SP114R	0.089	2.6	POSITIVE	ConfP-86	83.1	YES	TP287	2.7
537319	Month 3	SP114R	0.906	48.6	POSITIVE	ConfP-86	97.0	YES	TP287	3.7
537319	Month 6	SP114R	0.745	39.6	POSITIVE	ConfP-86	97.1	YES	TP114	3.7
537319	Month 9	SP114R	0.874	46.8	POSITIVE	ConfP-86	97.4	YES	TP114	3.7
537319	Month 12	SP114R	0.825	44.1	POSITIVE	ConfP-86	94.9	YES	TP114	3.7
537319	Month 18	SP114R	0.411	20.8	POSITIVE	ConfP-86	94.3	YES	TP114	3.7
537319	Month 24	SP114R	0.678	35.8	POSITIVE	ConfP-86	91.4	YES	TP114	2.7
537321	Baseline	SP115R	0.047	0.0	Negative					
537321	Month 1	SP115R	1.948	121.7	POSITIVE	ConfP-86	98.5	YES	TP115	4.7
537321	Month 3	SP115R	2.107	131.9	POSITIVE	ConfP-86	96.9	YES	TP115	4.7
537321	Month 6	SP115R	1.817	113.3	POSITIVE	ConfP-87	98.0	YES	TP115	4.7
537321	Month 9	SP115R	1.625	101.0	POSITIVE	ConfP-87	98.2	YES	TP116	4.7
537321	Month 12	SP115R	1.002	61.0	POSITIVE	ConfP-87	97.5	YES	TP116	4.7
537321	Month 18	SP115R	0.583	34.1	POSITIVE	ConfP-87	97.0	YES	TP116	3.7
537321	Month 24	SP115R	0.756	45.2	POSITIVE	ConfP-87	96.0	YES	TP116	4.7
537401	Baseline	SP27	0.046	0.1	Negative					
537401	Month 1	SP27	2.021	96.9	POSITIVE	ConfP-3	99.3	YES	TP11	3.7
537401	Month 3	SP27	1.006	47.2	POSITIVE	ConfP-23	98.8	YES	TP247	3.7
537401	Month 6	SP27	0.400	17.5	POSITIVE	ConfP-24	98.6	YES	TP247	2.7
537401	Month 9	SP28	0.312	13.8	POSITIVE	ConfP-24	96.9	YES	TP248	2.7
537401	Month 12	SP28	0.360	16.3	POSITIVE	ConfP-24	99.1	YES	TP248	2.7
537401	Month 18	SP28	0.375	17.1	POSITIVE	ConfP-24	98.7	YES	TP248	2.7
537401	Month 24	SP28	0.133	4.6	POSITIVE	ConfP-24	95.6	YES	TP248	2.7
537403	Baseline	SP28	0.043	0.0	Negative					
537403	Month 1	SP28	0.047	0.2	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537403	Month 3	SP28	0.553	26.2	POSITIVE	ConfP-4	100.0	YES	TP11	2.7
537403	Month 6	SP28	0.553	26.2	POSITIVE	ConfP-24	99.3	YES	TP248	2.7
537403	Month 9	SP28	0.174	6.7	POSITIVE	ConfP-24	99.3	YES	TP248	2.7
537403	Month 12	SP28	0.118	3.9	POSITIVE	ConfP-24	97.0	YES	TP249	2.7
537403	Month 18	SP28	0.071	1.4	Negative					
537403	Month 24	SP28	0.060	0.9	Negative					
537405	Baseline	SP115R	0.066	1.0	Negative					
537405	Month 1	SP115R	0.232	11.6	POSITIVE	ConfP-87	97.2	YES	TP116	3.7
537405	Month 3	SP115R	1.425	88.1	POSITIVE	ConfP-87	98.8	YES	TP116	4.7
537405	Month 6	SP115R	0.560	32.6	POSITIVE	ConfP-87	97.5	YES	TP117	3.7
537405	Month 9	SP116R	0.453	24.0	POSITIVE	ConfP-88	96.3	YES	TP118	3.7
537405	Month 12	SP116R	0.359	18.5	POSITIVE	ConfP-88	97.8	YES	TP118	3.7
537405	Month 18	SP116R	0.332	16.9	POSITIVE	ConfP-88	97.4	YES	TP118	3.7
537405	Month 24	SP116R	0.204	9.5	POSITIVE	ConfP-88	95.1	YES	TP118	2.7
537407	Baseline	SP116R	0.045	0.2	Negative					
537407	Month 1	SP116R	1.034	57.9	POSITIVE	ConfP-87	99.1	YES	TP117	3.7
537407	Month 3	SP116R	1.484	84.2	POSITIVE	ConfP-87	99.2	YES	TP117	3.7
537407	Month 6	SP116R	0.815	45.2	POSITIVE	ConfP-87	99.0	YES	TP117	3.7
537407	Month 9	SP116R	0.810	44.9	POSITIVE	ConfP-87	98.8	YES	TP117	3.7
537407	Month 12	SP116R	0.480	25.6	POSITIVE	ConfP-87	96.1	YES	TP117	3.7
537407	Month 18	SP116R	0.398	20.8	POSITIVE	ConfP-88	98.4	YES	TP118	3.7
537407	Month 24	SP116R	0.530	28.5	POSITIVE	ConfP-88	98.6	YES	TP118	3.7
537408	Baseline	SP117R	0.052	0.5	Negative					
537408	Month 1	SP117R	0.115	3.9	POSITIVE	ConfP-88	95.7	YES	TP119	2.7
537408	Month 3	SP117R	0.751	38.3	POSITIVE	ConfP-88	98.8	YES	TP119	3.7
537408	Month 6	SP117R	0.222	9.7	POSITIVE	ConfP-88	97.3	YES	TP119	2.7
537408	Month 9	SP117R	0.144	5.5	POSITIVE	ConfP-88	96.7	YES	TP119	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537408	Month 12	SP117R	0.114	3.8	POSITIVE	ConfP-88	94.6	YES	TP119	2.7
537408	Month 18	SP117R	0.137	5.1	POSITIVE	ConfP-88	97.1	YES	TP119	2.7
537408	Month 24	SP117R	0.117	4.0	POSITIVE	ConfP-88	94.8	YES	TP120	2.7
537410	Baseline	SP117R	0.052	0.5	Negative					
537410	Month 1	SP117R	0.346	16.4	POSITIVE	ConfP-89	98.6	YES	TP120	2.7
537410	Month 3	SP117R	2.235	118.7	POSITIVE	ConfP-89	99.5	YES	TP120	4.7
537410	Month 6	SP117R	2.016	106.8	POSITIVE	ConfP-89	99.7	YES	TP120	3.7
537410	Month 9	SP118R	1.157	62.9	POSITIVE	ConfP-89	99.6	YES	TP121	3.7
537410	Month 12	SP118R	1.067	57.8	POSITIVE	ConfP-89	99.6	YES	TP122	3.7
537410	Month 18	SP118R	0.518	26.8	POSITIVE	ConfP-89	98.9	YES	TP122	3.7
537410	Month 24	SP118R	0.775	41.3	POSITIVE	ConfP-90	99.4	YES	TP122	3.7
537412	Baseline	SP118R	0.044	0.1	Negative					
537412	Month 1	SP118R	0.311	15.1	POSITIVE	ConfP-89	98.9	YES	TP120	2.7
537412	Month 3	SP118R	1.019	55.1	POSITIVE	ConfP-89	99.6	YES	TP120	3.7
537412	Month 6	SP118R	0.392	19.7	POSITIVE	ConfP-89	99.4	YES	TP121	2.7
537412	Month 9	SP118R	0.209	9.4	POSITIVE	ConfP-89	98.9	YES	TP121	2.7
537412	Month 12	SP118R	0.310	15.1	POSITIVE	ConfP-89	99.4	YES	TP121	2.7
537412	Month 18	SP118R	0.227	10.4	POSITIVE	ConfP-89	98.2	YES	TP121	2.7
537412	Month 24	SP118R	0.341	16.8	POSITIVE	ConfP-89	99.4	YES	TP121	2.7
537414	Baseline	SP119R2	0.044	0.3	Negative					
537414	Month 1	SP119R2	0.188	10.2	POSITIVE	ConfP-90	98.1	YES	TP122	2.7
537414	Month 3	SP119R2	1.118	73.8	POSITIVE	ConfP-90	98.9	YES	TP122	3.7
537414	Month 6	SP119R2	0.300	17.8	POSITIVE	ConfP-90	99.4	YES	TP122	2.7
537414	Month 9	SP119R2	0.450	28.1	POSITIVE	ConfP-90	98.7	YES	TP123	3.7
537414	Month 12	SP119R2	0.230	13.1	POSITIVE	ConfP-90	99.4	YES	TP123	3.7
537414	Month 18	SP119R2	0.058	1.3	Negative					
537414	Month 24	SP119R2	0.046	0.5	Negative					
537502	Baseline	SP119R2	0.045	0.4	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537502	Month 1	SP119R2	0.790	51.3	POSITIVE	ConfP-90	99.3	YES	TP123	3.7
537502	Month 3	SP119R2	0.282	16.6	POSITIVE	ConfP-90	98.5	YES	TP123	2.7
537502	Month 6	SP119R2	0.504	31.8	POSITIVE	ConfP-90	97.7	YES	TP123	3.7
537502	Month 9	SP120R2	0.370	20.9	POSITIVE	ConfP-132	92.8	YES	TP287	3.7
537502	Month 12	SP120R2	0.296	16.2	POSITIVE	ConfP-91	96.9	YES	TP125	3.7
537502	Month 18	SP120R2	0.731	43.9	POSITIVE	ConfP-91	91.3	YES	TP125	3.7
537502	Month 24	SP120R2	0.654	39.0	POSITIVE	ConfP-91	80.4	YES	TP125	3.7
537504	Baseline	SP120R2	0.043	0.0	Negative					
537504	Month 1	SP120R2	0.303	16.6	POSITIVE	ConfP-90	94.4	YES	TP123	2.7
537504	Month 3	SP120R2	0.577	34.1	POSITIVE	ConfP-90	96.1	YES	TP124	3.7
537504	Month 6	SP120R2	0.374	21.1	POSITIVE	ConfP-90	93.9	YES	TP124	3.7
537504	Month 9	SP120R2	0.045	0.1	Negative					
537504	Month 12	SP120R2	0.267	14.3	POSITIVE	ConfP-91	91.4	YES	TP124	2.7
537504	Month 18	SP120R2	0.154	7.1	POSITIVE	ConfP-91	82.8	YES	TP124	2.7
537504	Month 24	SP120R2	0.111	4.3	POSITIVE	ConfP-91	77.9	YES	TP124	2.7
537506	Baseline	SP121R	0.044	0.1	Negative					
537506	Month 1	SP121R	0.183	10.4	POSITIVE	ConfP-91	96.0	YES	TP125	2.7
537506	Month 3	SP121R	0.463	31.1	POSITIVE	ConfP-91	98.3	YES	TP125	3.7
537506	Month 6	SP121R	0.239	14.5	POSITIVE	ConfP-91	96.3	YES	TP125	2.7
537506	Month 9	SP121R	0.242	14.8	POSITIVE	ConfP-91	96.2	YES	TP126	2.7
537506	Month 12	SP121R	0.116	5.5	POSITIVE	ConfP-91	94.0	YES	TP126	2.7
537506	Month 18	SP121R	0.153	8.2	POSITIVE	ConfP-91	93.4	YES	TP126	2.7
537506	Month 24	SP121R	0.096	4.0	POSITIVE	ConfP-91	91.8	YES	TP126	2.7
537508	Baseline	SP121R	0.046	0.3	Negative					
537508	Month 1	SP121R	0.226	13.6	POSITIVE	ConfP-92	96.3	YES	TP126	2.7
537508	Month 3	SP121R	0.993	70.2	POSITIVE	ConfP-92	99.0	YES	TP126	3.7
537508	Month 6	SP121R	0.634	43.7	POSITIVE	ConfP-92	98.7	YES	TP127	3.7
537508	Month 9	SP122R	0.044	0.1	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537508	Month 12	SP122R	0.334	19.7	POSITIVE	ConfP-92	97.2	YES	TP128	3.7
537508	Month 18	SP122R	0.128	5.7	POSITIVE	ConfP-92	97.9	YES	TP128	2.7
537508	Month 24	SP122R	0.467	28.7	POSITIVE	ConfP-92	97.8	YES	TP128	3.7
537511	Baseline	SP122R	0.047	0.3	Negative					
537511	Month 1	SP122R	0.704	44.7	POSITIVE	ConfP-92	98.5	YES	TP127	3.7
537511	Month 3	SP122R	1.357	88.8	POSITIVE	ConfP-92	99.4	YES	TP127	3.7
537511	Month 6	SP122R	0.472	29.0	POSITIVE	ConfP-92	98.7	YES	TP127	3.7
537511	Month 9	SP122R	0.637	40.2	POSITIVE	ConfP-92	98.0	YES	TP127	3.7
537511	Month 12	SP122R	0.293	16.9	POSITIVE	ConfP-92	96.6	YES	TP127	3.7
537511	Month 18	SP122R	0.215	11.6	POSITIVE	ConfP-92	97.1	YES	TP128	2.7
537511	Month 24	SP122R	0.215	11.6	POSITIVE	ConfP-92	95.8	YES	TP128	2.7
537512	Baseline	SP184	0.055	0.7	Negative					
537512	Baseline	SP184	0.063	1.2	Negative					
537512	Month 1	SP123R	2.277	130.2	POSITIVE	ConfP-93	98.8	YES	TP128	4.7
537512	Month 3	SP123R	1.188	66.8	POSITIVE	ConfP-93	99.2	YES	TP129	3.7
537512	Month 6	SP123R	0.294	14.7	POSITIVE	ConfP-93	98.3	YES	TP129	3.7
537512	Month 9	SP123R	0.044	0.1	Negative					
537512	Month 12	SP123R	0.169	7.4	POSITIVE	ConfP-93	96.1	YES	TP129	2.7
537512	Month 18	SP123R	0.288	14.3	POSITIVE	ConfP-93	98.2	YES	TP129	2.7
537512	Month 24	SP123R	0.203	9.4	POSITIVE	ConfP-93	97.6	YES	TP129	2.7
537606	Baseline	SP192	0.084	0.4	Negative					
537606	Month 1	SP192	0.943	37.7	POSITIVE	ConfP-141	98.8	YES	TP302	2.7
537606	Month 3	SP192	2.490	105.0	POSITIVE	ConfP-141	98.9	YES	TP302	3.7
537606	Month 6	SP192	2.232	93.7	POSITIVE	ConfP-141	99.6	YES	TP302	3.7
537606	Month 9					No sample received				
537606	Month 12	SP192	2.162	90.7	POSITIVE	ConfP-141	99.7	YES	TP302	3.7
537606	Month 18	SP192	0.357	12.3	POSITIVE	ConfP-141	96.2	YES	TP302	2.7
537606	Month 24	SP196	1.231	48.3	POSITIVE	ConfP-141	99.2	YES	TP302	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537901	Baseline	SP29	0.052	0.6	Negative					
537901	Month 1	SP29	0.708	42.0	POSITIVE	ConfP-24	99.5	YES	TP249	3.7
537901	Month 3	SP29	1.177	71.7	POSITIVE	ConfP-4	100.0	YES	TP11	3.7
537901	Month 6	SP29	0.294	15.9	POSITIVE	ConfP-24	99.1	YES	TP249	2.7
537901	Month 9	SP29	0.226	11.6	POSITIVE	ConfP-24	98.6	YES	TP249	2.7
537901	Month 12	SP29	0.462	26.5	POSITIVE	ConfP-24	98.9	YES	TP249	2.7
537901	Month 18	SP29	0.266	14.1	POSITIVE	ConfP-24	98.9	YES	TP249	2.7
537901	Month 24	SP29	0.430	24.5	POSITIVE	ConfP-25	99.6	YES	TP250	2.7
537902	Baseline	SP186	0.097	1.1	Negative					
537902	Month 1					No sample received				
537902	Month 3	SP186	1.048	45.6	POSITIVE	ConfP-138	99.4	YES	TP315	3.7
537902	Month 6	SP186	0.236	7.6	POSITIVE	ConfP-138	98.6	YES	TP293	2.7
537902	Month 9	SP186	0.167	4.4	POSITIVE	ConfP-138	100.0	YES	TP293	2.7
537902	Month 12	SP186	0.299	10.6	POSITIVE	ConfP-138	100.0	YES	TP293	2.7
537902	Month 18	SP186	0.173	4.7	POSITIVE	ConfP-138	100.0	YES	TP293	2.7
537902	Month 24	SP186	0.196	5.8	POSITIVE	ConfP-138	100.0	YES	TP293	2.7
537903	Baseline	SP193	0.102	1.4	Negative					
537903	Month 1	SP193	0.247	7.1	POSITIVE	ConfP-142	73.3	YES	TP303	2.7
537903	Month 3	SP193	2.724	104.8	POSITIVE	ConfP-142	99.8	YES	TP303	3.7
537903	Month 6	SP193	2.486	95.4	POSITIVE	ConfP-142	99.5	YES	TP303	3.7
537903	Month 9					No sample received				
537903	Month 12	SP193	2.906	112.0	POSITIVE	ConfP-142	98.8	YES	TP303	3.7
537903	Month 18	SP193	2.250	86.1	POSITIVE	ConfP-142	98.8	YES	TP303	3.7
537903	Month 24	SP193	2.582	99.2	POSITIVE	ConfP-142	99.3	YES	TP303	3.7
537906	Baseline	SP29	0.049	0.4	Negative					
537906	Month 1	SP29	0.611	35.9	POSITIVE	ConfP-25	99.8	YES	TP250	3.7
537906	Month 3	SP29	1.546	95.0	POSITIVE	ConfP-4	100.0	YES	TP11	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537906	Month 6	SP29	0.565	33.0	POSITIVE	ConfP-25	98.8	YES	TP250	2.7
537906	Month 9	SP30	0.266	14.8	POSITIVE	ConfP-25	99.1	YES	TP250	2.7
537906	Month 12	SP30	0.298	17.0	POSITIVE	ConfP-25	99.0	YES	TP250	2.7
537906	Month 18	SP30	0.151	7.0	POSITIVE	ConfP-25	98.2	YES	TP250	2.7
537906	Month 24	SP30	0.200	10.3	POSITIVE	ConfP-25	99.2	YES	TP251	2.7
537910	Baseline	SP124R	0.064	1.3	Negative					
537910	Month 1	SP124R	0.317	16.2	POSITIVE	ConfP-93	97.0	YES	TP130	2.7
537910	Month 3	SP124R	2.004	115.1	POSITIVE	ConfP-93	99.3	YES	TP130	4.7
537910	Month 6	SP124R	0.332	17.1	POSITIVE	ConfP-93	97.3	YES	TP130	2.7
537910	Month 9	SP124R	0.176	7.9	POSITIVE	ConfP-93	96.1	YES	TP130	2.7
537910	Month 12	SP124R	0.376	19.6	POSITIVE	ConfP-94	97.6	YES	TP131	2.7
537910	Month 18	SP124R	0.291	14.7	POSITIVE	ConfP-94	97.9	YES	TP131	2.7
537910	Month 24	SP124R	0.227	10.9	POSITIVE	ConfP-94	96.1	YES	TP131	2.7
537911	Baseline	SP123R	0.049	0.4	Negative					
537911	Month 1	SP123R	0.507	27.1	POSITIVE	ConfP-93	98.4	YES	TP129	3.7
537911	Month 3	SP123R	0.813	44.9	POSITIVE	ConfP-93	98.9	YES	TP130	3.7
537911	Month 6	SP123R	0.343	17.5	POSITIVE	ConfP-93	96.9	YES	TP130	3.7
537911	Month 9	SP124R	0.135	5.5	POSITIVE	ConfP-94	90.4	YES	TP131	2.7
537911	Month 12	SP124R	0.104	3.7	POSITIVE	ConfP-94	91.1	YES	TP131	2.7
537911	Month 18	SP124R	0.166	7.3	POSITIVE	ConfP-94	95.3	YES	TP131	2.7
537911	Month 24	SP124R	0.093	3.0	POSITIVE	ConfP-94	81.5	YES	TP132	2.7
537912	Baseline	SP125R	0.053	0.7	Negative					
537912	Month 1	SP125R	0.562	37.0	POSITIVE	ConfP-94	96.3	YES	TP132	2.7
537912	Month 3	SP125R	1.967	137.3	POSITIVE	ConfP-94	98.4	YES	TP132	3.7
537912	Month 6	SP125R	1.673	116.3	POSITIVE	ConfP-94	99.0	YES	TP132	3.7
537912	Month 9	SP125R	1.101	75.5	POSITIVE	ConfP-94	98.4	YES	TP132	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
537912	Month 12	SP125R	0.854	57.9	POSITIVE	ConfP-94	98.1	YES	TP132	3.7
537912	Month 18	SP125R	0.390	24.8	POSITIVE	ConfP-94	98.4	YES	TP133	2.7
537912	Month 24	SP125R	0.264	15.8	POSITIVE	ConfP-95	97.1	YES	TP133	2.7
538101	Baseline	SP125R	0.054	0.8	Negative					
538101	Month 1	SP125R	0.064	1.5	POSITIVE	ConfP-95	82.4	YES	TP133	2.7
538101	Month 3	SP125R	0.066	1.6	POSITIVE	ConfP-95	83.3	YES	TP133	<2.7
538101	Month 6	SP125R	1.065	72.9	POSITIVE	ConfP-95	99.0	YES	TP133	3.7
538101	Month 9	SP126R	0.198	10.9	POSITIVE	ConfP-95	99.1	YES	TP135	2.7
538101	Month 12	SP126R	0.275	16.3	POSITIVE	ConfP-96	99.5	YES	TP135	2.7
538101	Month 18	SP126R	0.149	7.5	POSITIVE	ConfP-96	97.8	YES	TP135	2.7
538101	Month 24	SP126R	0.366	22.7	POSITIVE	ConfP-96	99.2	YES	TP135	2.7
538102	Baseline	SP126R	0.066	1.7	POSITIVE	ConfP-95	68.2	YES	TP133	2.7
538102	Month 1	SP126R	0.566	36.7	POSITIVE	ConfP-95	96.0	YES	TP134	2.7
538102	Month 3	SP126R	2.112	145.1	POSITIVE	ConfP-95	98.9	YES	TP134	3.7
538102	Month 6	SP126R	0.342	21.0	POSITIVE	ConfP-95	98.5	YES	TP134	2.7
538102	Month 9	SP126R	1.004	67.4	POSITIVE	ConfP-95	96.5	YES	TP134	3.7
538102	Month 12	SP126R	1.812	124.0	POSITIVE	ConfP-95	99.4	YES	TP134	3.7
538102	Month 18	SP126R	1.376	93.5	POSITIVE	ConfP-95	97.4	YES	TP134	3.7
538102	Month 24	SP126R	1.217	82.3	POSITIVE	ConfP-95	98.3	YES	TP135	3.7
538201	Baseline	SP30	0.046	0.0	Negative					
538201	Month 1	SP30	0.146	6.7	POSITIVE	ConfP-25	98.5	YES	TP251	2.7
538201	Month 3	SP30	0.559	34.6	POSITIVE	ConfP-4	99.5	YES	TP12	3.7
538201	Month 6	SP30	0.177	8.8	POSITIVE	ConfP-25	97.4	YES	TP251	2.7
538201	Month 9	SP30	0.159	7.6	POSITIVE	ConfP-25	97.1	YES	TP251	2.7
538201	Month 12	SP30	0.109	4.2	POSITIVE	ConfP-25	96.0	YES	TP251	2.7
538201	Month 18	SP30	0.064	1.1	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
538201	Month 24	SP30	0.064	1.1	Negative					
538202	Baseline	SP31	0.054	0.7	Negative					
538202	Month 1	SP31	0.520	31.5	POSITIVE	ConfP-25	99.0	YES	TP251	3.7
538202	Month 3	SP31	1.377	88.1	POSITIVE	ConfP-4	100.0	YES	TP12	3.7
538202	Month 6	SP31	0.623	38.3	POSITIVE	ConfP-25	98.8	YES	TP252	2.7
538202	Month 9	SP31	0.711	44.1	POSITIVE	ConfP-26	99.2	YES	TP252	3.7
538202	Month 12	SP31	0.606	37.1	POSITIVE	ConfP-26	98.4	YES	TP252	2.7
538202	Month 18	SP31	0.473	28.4	POSITIVE	ConfP-26	98.9	YES	TP252	2.7
538202	Month 24	SP31	0.531	32.2	POSITIVE	ConfP-26	99.0	YES	TP252	2.7
538203	Baseline	SP127	0.047	0.4	Negative					
538203	Month 1	SP127	0.052	0.8	Negative					
538203	Month 3	SP127	0.171	9.0	POSITIVE	ConfP-96	97.0	YES	TP135	2.7
538203	Month 6	SP127	0.245	14.1	POSITIVE	ConfP-96	97.3	YES	TP136	2.7
538203	Month 9	SP127	0.176	9.3	POSITIVE	ConfP-96	97.6	YES	TP136	2.7
538203	Month 12	SP127	0.219	12.3	POSITIVE	ConfP-96	94.6	YES	TP136	2.7
538203	Month 18	SP127	0.238	13.6	POSITIVE	ConfP-96	96.8	YES	TP136	2.7
538203	Month 24	SP127	0.261	15.2	POSITIVE	ConfP-96	97.4	YES	TP136	2.7
543501	Baseline	SP31	0.053	0.6	Negative					
543501	Month 1	SP31	0.081	2.4	POSITIVE	ConfP-26	97.4	YES	TP252	2.7
543501	Month 3	SP31	0.313	17.8	POSITIVE	ConfP-26	99.5	YES	TP253	2.7
543501	Month 6	SP31	0.555	33.8	POSITIVE	ConfP-4	100.0	YES	TP12	2.7
543501	Month 9	SP32	0.146	7.2	POSITIVE	ConfP-26	99.0	YES	TP253	2.7
543501	Month 12	SP32	0.122	5.5	POSITIVE	ConfP-26	98.5	YES	TP253	2.7
543501	Month 18	SP32	0.280	16.7	POSITIVE	ConfP-26	99.1	YES	TP253	2.7
543501	Month 24	SP32	0.216	12.1	POSITIVE	ConfP-26	66.7	YES	TP253	2.7
543505	Baseline	SP190	0.077	0.1	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
543505	Month 1	SP190	0.177	4.0	POSITIVE	ConfP-135	100.0	YES	TP315	2.7
543505	Month 3					No sample received				
543505	Month 6	SP190	0.226	6.0	POSITIVE	ConfP-135	100.0	YES	TP317	2.7
543505	Month 9	SP190	0.156	3.2	POSITIVE	ConfP-135	100.0	YES	TP294	<2.7
543505	Month 12	SP190	0.134	2.3	POSITIVE	ConfP-135	100.0	YES	TP294	<2.7
543505	Month 18	SP190	0.180	4.2	POSITIVE	ConfP-135	100.0	YES	TP294	2.7
543505	Month 24	SP190	0.196	4.8	POSITIVE	ConfP-135	100.0	YES	TP294	2.7
551001	Baseline	SP190	0.091	0.6	Negative					
551001	Month 1	SP190	0.477	15.9	POSITIVE	ConfP-147	98.6	YES	TP315	2.7
551001	Month 3					No sample received				
551001	Month 6	SP190	1.134	42.0	POSITIVE	ConfP-135	100.0	YES	TP294	2.7
551001	Month 9	SP190	1.047	38.5	POSITIVE	ConfP-135	97.2	YES	TP294	2.7
551001	Month 12	SP190	1.250	46.6	POSITIVE	ConfP-135	95.5	YES	TP295	3.7
551001	Month 18	SP190	0.676	23.8	POSITIVE	ConfP-135	92.0	YES	TP295	2.7
551001	Month 24	SP196	1.342	52.9	POSITIVE	ConfP-135	100.0	YES	TP295	2.7
551002	Baseline	SP127	0.057	1.1	Negative					
551002	Month 1	SP127	1.593	107.0	POSITIVE	ConfP-96	99.4	YES	TP136	3.7
551002	Month 3	SP127	0.896	58.9	POSITIVE	ConfP-96	98.9	YES	TP137	3.7
551002	Month 6	SP127	0.640	41.3	POSITIVE	ConfP-96	97.4	YES	TP137	3.7
551002	Month 9	SP128	0.793	44.9	POSITIVE	ConfP-97	97.4	YES	TP138	3.7
551002	Month 12	SP128	0.753	42.5	POSITIVE	ConfP-97	98.9	YES	TP138	3.7
551002	Month 18	SP128	1.147	66.0	POSITIVE	ConfP-97	98.8	YES	TP138	3.7
551002	Month 24	SP128	0.824	46.7	POSITIVE	ConfP-97	98.4	YES	TP139	3.7
551005	Baseline	SP128	0.056	0.9	Negative					
551005	Month 1	SP128	0.340	17.9	POSITIVE	ConfP-96	98.6	YES	TP137	2.7
551005	Month 3	SP128	2.372	139.2	POSITIVE	ConfP-97	99.4	YES	TP137	4.7
551005	Month 6	SP128	0.777	43.9	POSITIVE	ConfP-97	98.5	YES	TP137	3.7
551005	Month 9	SP128	0.893	50.9	POSITIVE	ConfP-97	98.6	YES	TP137	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
551005	Month 12	SP128	1.659	96.6	POSITIVE	ConfP-97	99.3	YES	TP138	3.7
551005	Month 18	SP128	0.571	31.6	POSITIVE	ConfP-97	98.1	YES	TP138	3.7
551005	Month 24	SP128	0.390	20.8	POSITIVE	ConfP-97	96.9	YES	TP138	3.7
551206	Baseline	SP186	0.083	0.5	Negative					
551206	Month 1					No sample received				
551206	Month 3	SP186	1.784	80.1	POSITIVE	ConfP-138	99.6	YES	TP295	3.7
551206	Month 6	SP186	0.947	40.9	POSITIVE	ConfP-138	99.4	YES	TP295	2.7
551206	Month 9	SP186	0.498	19.9	POSITIVE	ConfP-138	98.4	YES	TP295	2.7
551206	Month 12	SP186	0.473	18.7	POSITIVE	ConfP-138	100.0	YES	TP297	2.7
551206	Month 18	SP196	0.555	20.4	POSITIVE	ConfP-138	99.1	YES	TP297	2.7
551206	Month 24	SP196	0.464	16.7	POSITIVE	ConfP-138	98.0	YES	TP297	2.7
551207	Baseline	SP187	0.073	0.0	Negative					
551207	Month 1					No sample received				
551207	Month 3	SP187	1.426	63.4	POSITIVE	ConfP-139	100.0	YES	TP315	3.7
551207	Month 6	SP187	1.063	46.3	POSITIVE	ConfP-139	99.7	YES	TP297	3.7
551207	Month 9	SP187	0.365	13.5	POSITIVE	ConfP-139	99.3	YES	TP297	2.7
551207	Month 12	SP187	0.162	3.9	POSITIVE	ConfP-139	100.0	YES	TP297	2.7
551207	Month 18	SP199	0.584	28.1	POSITIVE	ConfP-139	99.1	YES	TP315	2.7
551207	Month 24	SP187	0.145	3.1	POSITIVE	ConfP-139	95.2	YES	TP316	2.7
551208	Baseline	SP187	0.083	0.2	Negative					
551208	Month 1					No sample received				
551208	Month 3	SP187	0.812	34.5	POSITIVE	ConfP-139	99.8	YES	TP304	2.7
551208	Month 6	SP199	0.426	19.3	POSITIVE	ConfP-139	100.0	YES	TP304	2.7
551208	Month 9	SP199	0.707	34.9	POSITIVE	ConfP-139	98.4	YES	TP304	2.7
551208	Month 12	SP187	0.511	20.4	POSITIVE	ConfP-139	97.6	YES	TP304	2.7
551208	Month 18	SP187	0.299	10.4	POSITIVE	ConfP-139	98.4	YES	TP304	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
551208	Month 24	SP196	0.642	24.0	POSITIVE	ConfP-139	98.4	YES	TP304	2.7
571001	Baseline	SP129	0.049	0.5	Negative					
571001	Month 1	SP129	0.539	28.7	POSITIVE	ConfP-97	98.1	YES	TP139	3.7
571001	Month 3	SP129	0.452	23.7	POSITIVE	ConfP-97	97.6	YES	TP139	3.7
571001	Month 6	SP129	0.402	20.8	POSITIVE	ConfP-97	98.3	YES	TP139	2.7
571001	Month 9	SP129	0.092	2.9	POSITIVE	ConfP-98	92.7	YES	TP139	2.7
571001	Month 12	SP129	0.146	6.1	POSITIVE	ConfP-98	96.0	YES	TP139	2.7
571001	Month 18	SP129	0.154	6.5	POSITIVE	ConfP-98	96.0	YES	TP140	2.7
571001	Month 24	SP129	0.105	3.7	POSITIVE	ConfP-98	96.1	YES	TP140	2.7
571002	Baseline	SP129	0.051	0.6	Negative					
571002	Month 1	SP129	1.999	112.9	POSITIVE	ConfP-98	98.2	YES	TP140	3.7
571002	Month 3	SP129	1.045	57.9	POSITIVE	ConfP-98	99.1	YES	TP140	3.7
571002	Month 6	SP129	0.127	5.0	POSITIVE	ConfP-98	97.8	YES	TP140	2.7
571002	Month 9	SP130	0.432	23.0	POSITIVE	ConfP-99	98.8	YES	TP142	2.7
571002	Month 12	SP130	0.727	40.4	POSITIVE	ConfP-99	98.8	YES	TP142	3.7
571002	Month 18	SP130	0.675	37.4	POSITIVE	ConfP-99	98.8	YES	TP142	2.7
571002	Month 24	SP130	1.119	63.5	POSITIVE	ConfP-99	99.5	YES	TP142	3.7
571101	Baseline	SP197	0.101	0.6	Negative					
571101	Month 1	SP197	1.117	46.9	POSITIVE	ConfP-145	98.9	YES	TP305	2.7
571101	Month 3	SP197	2.893	127.9	POSITIVE	ConfP-145	99.0	YES	TP305	3.7
571101	Month 6	SP197	3.019	133.6	POSITIVE	ConfP-145	98.5	YES	TP305	3.7
571101	Month 9	SP197	2.113	92.3	POSITIVE	ConfP-145	99.3	YES	TP305	3.7
571101	Month 12					No sample received				
571101	Month 18	SP197	0.738	29.7	POSITIVE	ConfP-145	96.0	YES	TP305	2.7
571101	Month 24	SP197	1.124	47.3	POSITIVE	ConfP-145	99.3	YES	TP305	2.7
571103	Baseline	SP130	0.056	0.9	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
571103	Month 1	SP130	1.050	59.5	POSITIVE	ConfP-98	98.6	YES	TP140	3.7
571103	Month 3	SP130	2.181	126.1	POSITIVE	ConfP-98	97.9	YES	TP141	3.7
571103	Month 6	SP130	1.502	86.1	POSITIVE	ConfP-98	96.4	YES	TP287	3.7
571103	Month 9	SP130	0.607	33.4	POSITIVE	ConfP-98	94.7	YES	TP141	3.7
571103	Month 12	SP130	0.380	20.0	POSITIVE	ConfP-98	94.3	YES	TP287	2.7
571103	Month 18	SP130	0.536	29.2	POSITIVE	ConfP-98	96.9	YES	TP141	2.7
571103	Month 24	SP130	0.184	8.4	POSITIVE	ConfP-99	94.9	YES	TP288	3.7
571104	Baseline	SP131	0.047	0.3	Negative					
571104	Month 1	SP131	0.364	21.2	POSITIVE	ConfP-99	99.0	YES	TP142	2.7
571104	Month 3	SP131	1.527	97.6	POSITIVE	ConfP-99	99.5	YES	TP142	4.7
571104	Month 6	SP131	0.685	42.3	POSITIVE	ConfP-99	98.9	YES	TP143	3.7
571104	Month 9	SP131	0.441	26.2	POSITIVE	ConfP-99	98.8	YES	TP143	3.7
571104	Month 12	SP131	0.659	40.6	POSITIVE	ConfP-99	98.8	YES	TP143	3.7
571104	Month 18	SP131	0.773	48.1	POSITIVE	ConfP-99	99.1	YES	TP143	3.7
571104	Month 24	SP131	0.553	33.6	POSITIVE	ConfP-99	98.9	YES	TP143	3.7
571203	Baseline	SP131	0.045	0.2	Negative					
571203	Month 1	SP131	0.997	62.8	POSITIVE	ConfP-99	99.3	YES	TP143	3.7
571203	Month 3	SP131	1.270	80.7	POSITIVE	ConfP-100	97.6	YES	TP144	3.7
571203	Month 6	SP131	0.648	39.8	POSITIVE	ConfP-100	98.5	YES	TP144	3.7
571203	Month 9	SP132	0.493	26.4	POSITIVE	ConfP-100	99.0	YES	TP145	3.7
571203	Month 12	SP132	0.203	9.4	POSITIVE	ConfP-100	98.3	YES	TP145	2.7
571203	Month 18	SP132	0.152	6.4	POSITIVE	ConfP-100	98.0	YES	TP145	2.7
571203	Month 24	SP132	0.089	2.8	POSITIVE	ConfP-100	96.1	YES	TP146	2.7
571204	Baseline	SP132	0.052	0.6	Negative					
571204	Month 1	SP132	0.270	13.4	POSITIVE	ConfP-100	97.6	YES	TP144	2.7
571204	Month 3	SP132	1.202	68.0	POSITIVE	ConfP-100	99.4	YES	TP144	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
571204	Month 6	SP132	0.592	32.2	POSITIVE	ConfP-100	98.7	YES	TP144	3.7
571204	Month 9	SP132	0.735	40.6	POSITIVE	ConfP-100	99.3	YES	TP144	3.7
571204	Month 12	SP132	0.630	34.5	POSITIVE	ConfP-100	99.0	YES	TP145	3.7
571204	Month 18	SP132	0.358	18.5	POSITIVE	ConfP-100	98.9	YES	TP145	2.7
571204	Month 24	SP132	0.378	19.7	POSITIVE	ConfP-100	98.7	YES	TP145	2.7
571207	Baseline	SP133	0.045	0.2	Negative					
571207	Month 1	SP133	0.044	0.1	Negative					
571207	Month 3	SP133	0.271	12.6	POSITIVE	ConfP-101	99.3	YES	TP146	2.7
571207	Month 6	SP133	0.167	6.9	POSITIVE	ConfP-101	98.6	YES	TP146	2.7
571207	Month 9	SP133	0.146	5.7	POSITIVE	ConfP-101	97.5	YES	TP146	2.7
571207	Month 12	SP133	0.122	4.4	POSITIVE	ConfP-101	97.6	YES	TP146	2.7
571207	Month 18	SP133	0.073	1.7	POSITIVE	ConfP-101	90.3	YES	TP146	2.7
571207	Month 24	SP133	0.060	1.0	Negative					
571208	Baseline	SP133	0.048	0.3	Negative					
571208	Month 1	SP133	0.105	3.5	POSITIVE	ConfP-101	96.3	YES	TP147	2.7
571208	Month 3	SP133	0.245	11.2	POSITIVE	ConfP-101	99.0	YES	TP147	2.7
571208	Month 6	SP133	0.079	2.0	POSITIVE	ConfP-101	93.8	YES	TP147	2.7
571208	Month 9	SP134	0.128	5.4	POSITIVE	ConfP-102	99.2	YES	TP148	2.7
571208	Month 12	SP134	0.097	3.5	POSITIVE	ConfP-102	97.9	YES	TP148	2.7
571208	Month 18	SP134	0.067	1.6	POSITIVE	ConfP-102	96.2	YES	TP149	2.7
571208	Month 24	SP134	0.065	1.5	POSITIVE	ConfP-102	100.0	YES	TP149	2.7
582601	Baseline	SP134	0.047	0.3	Negative					
582601	Month 1	SP134	0.341	18.9	POSITIVE	ConfP-101	97.6	YES	TP147	2.7
582601	Month 3	SP134	0.690	41.1	POSITIVE	ConfP-101	98.6	YES	TP147	3.7
582601	Month 6	SP134	0.253	13.4	POSITIVE	ConfP-101	95.3	YES	TP147	2.7
582601	Month 9	SP134	0.234	12.2	POSITIVE	ConfP-101	95.0	YES	TP148	2.7
582601	Month 12	SP134	0.090	3.0	POSITIVE	ConfP-101	86.4	YES	TP148	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582601	Month 18	SP134	0.201	10.1	POSITIVE	ConfP-102	95.3	YES	TP148	2.7
582601	Month 24	SP134	0.180	8.7	POSITIVE	ConfP-102	95.6	YES	TP148	2.7
582603	Baseline	SP135R	0.047	0.2	Negative					
582603	Month 1	SP135R	0.069	1.3	Negative					
582603	Month 3	SP135R	1.032	50.6	POSITIVE	ConfP-102	99.5	YES	TP149	3.7
582603	Month 6	SP135R	0.448	20.7	POSITIVE	ConfP-102	98.8	YES	TP149	3.7
582603	Month 9	SP135R	0.307	13.5	POSITIVE	ConfP-102	99.2	YES	TP149	2.7
582603	Month 12	SP135R	0.210	8.5	POSITIVE	ConfP-102	98.3	YES	TP149	2.7
582603	Month 18	SP135R	0.109	3.4	POSITIVE	ConfP-102	97.0	YES	TP150	2.7
582603	Month 24	SP135R	0.084	2.1	POSITIVE	ConfP-102	95.7	YES	TP150	2.7
582605	Baseline	SP135R	0.056	0.7	Negative					
582605	Month 1	SP135R	0.704	33.8	POSITIVE	ConfP-102	98.5	YES	TP150	3.7
582605	Month 3	SP135R	0.255	10.8	POSITIVE	ConfP-103	95.1	YES	TP150	2.7
582605	Month 6	SP135R	0.130	4.4	POSITIVE	ConfP-103	88.7	YES	TP150	2.7
582605	Month 9	SP136R	0.109	3.5	POSITIVE	ConfP-103	93.4	YES	TP152	2.7
582605	Month 12	SP136R	0.086	2.3	POSITIVE	ConfP-103	87.2	YES	TP152	2.7
582605	Month 18	SP136R	0.069	1.4	Negative					
582605	Month 24	SP136R	0.092	2.6	POSITIVE	ConfP-103	94.6	YES	TP152	2.7
582606	Baseline	SP136R	0.046	0.2	Negative					
582606	Month 1	SP136R	0.420	19.6	POSITIVE	ConfP-103	99.0	YES	TP150	2.7
582606	Month 3	SP136R	1.235	61.7	POSITIVE	ConfP-103	99.0	YES	TP151	3.7
582606	Month 6	SP136R	0.445	20.8	POSITIVE	ConfP-103	99.0	YES	TP151	2.7
582606	Month 9	SP136R	0.616	29.7	POSITIVE	ConfP-103	99.5	YES	TP151	3.7
582606	Month 12	SP136R	0.689	33.5	POSITIVE	ConfP-103	99.5	YES	TP151	3.7
582606	Month 18	SP136R	0.323	14.5	POSITIVE	ConfP-103	99.5	YES	TP151	2.7
582606	Month 24	SP136R	0.265	11.5	POSITIVE	ConfP-103	99.5	YES	TP151	2.7
582609	Baseline	SP137R	0.061	0.8	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582609	Month 1	SP137R	1.335	65.0	POSITIVE	ConfP-103	91.4	YES	TP152	3.7
582609	Month 3	SP137R	1.483	72.4	POSITIVE	ConfP-104	98.9	YES	TP152	3.7
582609	Month 6	SP137R	0.268	11.2	POSITIVE	ConfP-104	94.4	YES	TP152	2.7
582609	Month 9	SP137R	0.341	14.9	POSITIVE	ConfP-104	97.4	YES	TP153	2.7
582609	Month 12	SP137R	0.610	28.5	POSITIVE	ConfP-104	98.2	YES	TP153	2.7
582609	Month 18	SP137R	0.745	35.3	POSITIVE	ConfP-104	97.6	YES	TP153	3.7
582609	Month 24	SP137R	0.932	44.7	POSITIVE	ConfP-104	98.5	YES	TP153	3.7
582611	Baseline	SP137R	0.048	0.2	Negative					
582611	Month 1	SP137R	0.387	17.2	POSITIVE	ConfP-104	98.7	YES	TP153	2.7
582611	Month 3	SP137R	1.241	60.3	POSITIVE	ConfP-104	99.6	YES	TP153	3.7
582611	Month 6	SP137R	0.454	20.6	POSITIVE	ConfP-104	99.3	YES	TP154	3.7
582611	Month 9	SP138R	0.438	19.9	POSITIVE	ConfP-105	99.3	YES	TP155	3.7
582611	Month 12	SP138R	0.255	10.7	POSITIVE	ConfP-105	99.6	YES	TP155	3.7
582611	Month 18	SP138R	0.367	16.3	POSITIVE	ConfP-105	98.9	YES	TP155	3.7
582611	Month 24	SP138R	0.150	5.4	POSITIVE	ConfP-105	97.7	YES	TP155	3.7
582613	Baseline	SP138R	0.051	0.4	Negative					
582613	Month 1	SP138R	0.122	4.0	POSITIVE	ConfP-104	92.9	YES	TP154	2.7
582613	Month 3	SP138R	0.230	9.4	POSITIVE	ConfP-104	93.6	YES	TP154	2.7
582613	Month 6	SP138R	0.099	2.8	POSITIVE	ConfP-104	93.6	YES	TP154	2.7
582613	Month 9	SP138R	0.076	1.7	POSITIVE	ConfP-104	86.3	YES	TP154	2.7
582613	Month 12	SP138R	0.082	2.0	POSITIVE	ConfP-105	93.1	YES	TP154	2.7
582613	Month 18	SP138R	0.066	1.2	Negative					
582613	Month 24	SP138R	0.074	1.6	POSITIVE	ConfP-105	92.7	YES	TP155	2.7
582614	Baseline	SP139R	0.044	0.2	Negative					
582614	Month 1	SP139R	0.180	8.4	POSITIVE	ConfP-105	97.7	YES	TP155	3.7
582614	Month 3	SP139R	0.485	27.0	POSITIVE	ConfP-105	99.3	YES	TP156	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582614	Month 6	SP139R	0.120	4.8	POSITIVE	ConfP-105	97.2	YES	TP156	2.7
582614	Month 9	SP139R	0.087	2.8	POSITIVE	ConfP-105	96.8	YES	TP156	2.7
582614	Month 12	SP139R	0.109	4.1	POSITIVE	ConfP-105	98.6	YES	TP156	2.7
582614	Month 18	SP139R	0.148	6.5	POSITIVE	ConfP-105	98.8	YES	TP156	2.7
582614	Month 24	SP139R	0.085	2.7	POSITIVE	ConfP-105	94.5	YES	TP156	2.7
582615	Baseline	SP139R	0.044	0.2	Negative					
582615	Month 1	SP139R	0.146	6.4	POSITIVE	ConfP-106	98.6	YES	TP157	2.7
582615	Month 3	SP139R	0.387	21.0	POSITIVE	ConfP-106	99.3	YES	TP157	3.7
582615	Month 6	SP139R	0.206	10.0	POSITIVE	ConfP-106	99.6	YES	TP157	2.7
582615	Month 9	SP140R	0.287	15.1	POSITIVE	ConfP-106	98.9	YES	TP158	2.7
582615	Month 12	SP140R	0.143	6.3	POSITIVE	ConfP-106	98.4	YES	TP158	2.7
582615	Month 18	SP140R	0.127	5.4	POSITIVE	ConfP-106	98.4	YES	TP159	2.7
582615	Month 24	SP140R	0.139	6.1	POSITIVE	ConfP-107	97.6	YES	TP159	2.7
582802	Baseline	SP193	0.096	1.1	Negative					
582802	Month 1	SP193	2.023	77.2	POSITIVE	ConfP-142	99.6	YES	TP306	3.7
582802	Month 3	SP193	1.789	67.9	POSITIVE	ConfP-142	99.5	YES	TP306	3.7
582802	Month 6	SP193	1.409	52.9	POSITIVE	ConfP-142	99.1	YES	TP306	3.7
582802	Month 9					No sample received				
582802	Month 12	SP193	1.201	44.7	POSITIVE	ConfP-142	99.3	YES	TP306	2.7
582802	Month 18	SP193	1.010	37.2	POSITIVE	ConfP-142	99.1	YES	TP306	2.7
582802	Month 24	SP196	0.451	16.1	POSITIVE	ConfP-142	97.9	YES	TP306	2.7
582804	Baseline	SP194	0.095	1.4	Negative					
582804	Month 1	SP194	0.707	25.7	POSITIVE	ConfP-143	98.6	YES	TP307	2.7
582804	Month 3	SP194	1.682	64.5	POSITIVE	ConfP-143	99.9	YES	TP307	3.7
582804	Month 6	SP194	0.794	29.2	POSITIVE	ConfP-143	99.8	YES	TP307	2.7
582804	Month 9					No sample received				

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582804	Month 12	SP194	0.645	23.3	POSITIVE	ConfP-143	100.0	YES	TP307	2.7
582804	Month 18	SP194	0.868	32.1	POSITIVE	ConfP-143	98.7	YES	TP307	2.7
582804	Month 24	SP194	0.997	37.3	POSITIVE	ConfP-143	99.0	YES	TP307	2.7
582807	Baseline	SP140R	0.044	0.3	Negative					
582807	Month 1	SP140R	1.951	116.4	POSITIVE	ConfP-106	98.9	YES	TP157	4.7
582807	Month 3	SP140R	1.730	103.0	POSITIVE	ConfP-106	98.9	YES	TP157	4.7
582807	Month 6	SP140R	0.924	53.9	POSITIVE	ConfP-106	98.9	YES	TP157	3.7
582807	Month 9	SP140R	0.565	32.0	POSITIVE	ConfP-106	98.9	YES	TP158	3.7
582807	Month 12	SP140R	0.590	33.6	POSITIVE	ConfP-106	99.4	YES	TP158	3.7
582807	Month 18	SP140R	0.536	30.3	POSITIVE	ConfP-106	99.1	YES	TP158	3.7
582807	Month 24	SP140R	0.483	27.0	POSITIVE	ConfP-106	98.6	YES	TP158	3.7
582810	Baseline	SP198	0.092	0.5	Negative					
582810	Month 1	SP198	1.619	79.4	POSITIVE	ConfP-146	100.0	YES	TP313	3.7
582810	Month 3	SP198	1.559	76.3	POSITIVE	ConfP-146	100.0	YES	TP313	3.7
582810	Month 6	SP198	1.086	51.8	POSITIVE	ConfP-146	100.0	YES	TP313	2.7
582810	Month 9	SP198	0.843	39.3	POSITIVE	ConfP-146	100.0	YES	TP313	2.7
582810	Month 12	SP198	0.776	35.8	POSITIVE	ConfP-146	100.0	YES	TP313	2.7
582810	Month 18					No sample received				
582810	Month 24	SP199	0.358	15.5	POSITIVE	ConfP-146	100.0	YES	TP313	2.7
582811	Baseline	SP141R	0.049	0.4	Negative					
582811	Month 1	SP141R	0.599	33.4	POSITIVE	ConfP-107	99.6	YES	TP159	3.7
582811	Month 3	SP141R	1.334	77.4	POSITIVE	ConfP-107	99.5	YES	TP159	3.7
582811	Month 6	SP141R	0.872	49.7	POSITIVE	ConfP-107	99.5	YES	TP159	3.7
582811	Month 9	SP141R	0.450	24.4	POSITIVE	ConfP-107	98.8	YES	TP159	2.7
582811	Month 12	SP141R	0.443	24.0	POSITIVE	ConfP-107	98.6	YES	TP160	3.7
582811	Month 18	SP141R	0.375	20.0	POSITIVE	ConfP-107	98.4	YES	TP160	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582811	Month 24	SP141R	0.228	11.1	POSITIVE	ConfP-107	97.6	YES	TP160	2.7
582812	Baseline	SP191	0.083	0.5	Negative					
582812	Month 1	SP191	0.808	29.5	POSITIVE	ConfP-136	100.0	YES	TP312	2.7
582812	Month 3	SP191	2.054	79.4	POSITIVE	ConfP-136	99.6	YES	TP312	3.7
582812	Month 6					No sample received				
582812	Month 9	SP191	0.886	32.6	POSITIVE	ConfP-136	99.6	YES	TP312	2.7
582812	Month 12	SP191	0.620	22.0	POSITIVE	ConfP-136	100.0	YES	TP312	2.7
582812	Month 18	SP191	0.609	21.5	POSITIVE	ConfP-136	98.8	YES	TP312	2.7
582812	Month 24	SP196	1.373	54.2	POSITIVE	ConfP-136	99.7	YES	TP312	2.7
582902	Baseline	SP141R	0.051	0.5	Negative					
582902	Month 1	SP141R	0.416	22.4	POSITIVE	ConfP-107	99.3	YES	TP160	2.7
582902	Month 3	SP141R	1.944	114.0	POSITIVE	ConfP-107	97.8	YES	TP160	4.7
582902	Month 6	SP141R	1.050	60.4	POSITIVE	ConfP-107	98.3	YES	TP160	3.7
582902	Month 9	SP142R	0.404	22.2	POSITIVE	ConfP-108	98.0	YES	TP162	2.7
582902	Month 12	SP142R	0.322	17.2	POSITIVE	ConfP-108	98.6	YES	TP162	2.7
582902	Month 18	SP142R	0.435	24.1	POSITIVE	ConfP-108	97.5	YES	TP162	2.7
582902	Month 24	SP142R	0.203	9.9	POSITIVE	ConfP-108	97.8	YES	TP162	2.7
582906	Baseline	SP142R	0.044	0.1	Negative					
582906	Month 1	SP142R	0.090	2.9	POSITIVE	ConfP-107	93.9	YES	TP161	2.7
582906	Month 3	SP142R	0.491	27.5	POSITIVE	ConfP-107	99.4	YES	TP161	3.7
582906	Month 6	SP142R	0.210	10.3	POSITIVE	ConfP-108	98.2	YES	TP161	2.7
582906	Month 9	SP142R	0.127	5.2	POSITIVE	ConfP-108	98.5	YES	TP161	2.7
582906	Month 12	SP142R	0.062	1.2	Negative					
582906	Month 18	SP142R	0.130	5.4	POSITIVE	ConfP-108	98.4	YES	TP161	2.7
582906	Month 24	SP142R	0.084	2.6	POSITIVE	ConfP-108	95.6	YES	TP161	2.7
582907	Baseline	SP143R	0.050	0.5	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582907	Month 1	SP143R	0.096	3.4	POSITIVE	ConfP-108	93.3	YES	TP162	2.7
582907	Month 3	SP143R	0.314	17.1	POSITIVE	ConfP-108	98.7	YES	TP162	2.7
582907	Month 6	SP143R	0.098	3.5	POSITIVE	ConfP-108	95.8	YES	TP163	2.7
582907	Month 9	SP143R	0.059	1.1	Negative					
582907	Month 12	SP143R	0.125	5.2	POSITIVE	ConfP-108	98.5	YES	TP163	2.7
582907	Month 18	SP143R	0.056	0.9	Negative					
582907	Month 24	SP143R	0.074	2.0	POSITIVE	ConfP-108	87.5	YES	TP163	2.7
582908	Baseline	SP143R	0.049	0.4	Negative					
582908	Month 1	SP143R	0.092	3.1	POSITIVE	ConfP-109	98.5	YES	TP163	2.7
582908	Month 3	SP143R	0.522	28.2	POSITIVE	ConfP-109	99.8	YES	TP163	3.7
582908	Month 6	SP143R	0.480	27.6	POSITIVE	ConfP-109	99.8	YES	TP163	2.7
582908	Month 9	SP144R	0.153	6.8	POSITIVE	ConfP-109	99.3	YES	TP165	2.7
582908	Month 12	SP144R	0.088	2.8	POSITIVE	ConfP-109	92.7	YES	TP165	2.7
582908	Month 18	SP144R	0.074	2.0	POSITIVE	ConfP-110	86.2	YES	TP165	2.7
582908	Month 24	SP144R	0.059	1.0	Negative					
582911	Baseline	SP144R	0.068	1.6	POSITIVE	ConfP-109	86.4	YES	TP164	2.7
582911	Month 1	SP144R	0.117	4.6	POSITIVE	ConfP-109	95.6	YES	TP164	2.7
582911	Month 3	SP144R	1.322	78.0	POSITIVE	ConfP-109	99.7	YES	TP164	3.7
582911	Month 6	SP144R	1.322	78.0	POSITIVE	ConfP-109	99.5	YES	TP164	3.7
582911	Month 9	SP144R	0.306	16.1	POSITIVE	ConfP-109	98.7	YES	TP164	2.7
582911	Month 12	SP144R	0.920	53.5	POSITIVE	ConfP-109	99.8	YES	TP164	3.7
582911	Month 18	SP144R	0.177	8.2	POSITIVE	ConfP-109	99.4	YES	TP165	2.7
582911	Month 24	SP144R	0.526	29.5	POSITIVE	ConfP-109	99.6	YES	TP165	2.7
582917	Baseline	SP145	0.048	0.3	Negative					
582917	Month 1	SP145	1.211	61.8	POSITIVE	ConfP-110	99.3	YES	TP165	3.7
582917	Month 3	SP145	1.641	84.5	POSITIVE	ConfP-110	99.5	YES	TP166	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
582917	Month 6	SP145	1.187	60.5	POSITIVE	ConfP-110	99.0	YES	TP166	3.7
582917	Month 9	SP145	1.807	93.3	POSITIVE	ConfP-110	98.9	YES	TP166	3.7
582917	Month 12	SP145	1.861	96.1	POSITIVE	ConfP-110	99.4	YES	TP166	3.7
582917	Month 18	SP145	0.357	16.6	POSITIVE	ConfP-110	97.9	YES	TP166	2.7
582917	Month 24	SP145	0.232	10.0	POSITIVE	ConfP-110	95.8	YES	TP288	2.7
583101	Baseline	SP145	0.049	0.4	Negative					
583101	Month 1	SP145	1.359	69.6	POSITIVE	ConfP-110	99.8	YES	TP167	3.7
583101	Month 3	SP145	1.176	59.9	POSITIVE	ConfP-110	99.7	YES	TP167	3.7
583101	Month 6	SP145	1.061	53.9	POSITIVE	ConfP-110	99.8	YES	TP167	3.7
583101	Month 9	SP146	0.361	17.7	POSITIVE	ConfP-111	99.2	YES	TP168	3.7
583101	Month 12	SP146	0.577	29.7	POSITIVE	ConfP-111	99.5	YES	TP169	3.7
583101	Month 18	SP146	1.063	56.7	POSITIVE	ConfP-111	99.5	YES	TP169	2.7
583101	Month 24	SP146	0.430	21.6	POSITIVE	ConfP-111	99.3	YES	TP169	2.7
583104	Baseline	SP146	0.083	2.3	POSITIVE	ConfP-110	82.5	YES	TP167	2.7
583104	Month 1	SP146	0.604	31.2	POSITIVE	ConfP-110	98.9	YES	TP167	2.7
583104	Month 3	SP146	1.985	107.8	POSITIVE	ConfP-111	99.1	YES	TP167	3.7
583104	Month 6	SP146	0.759	39.8	POSITIVE	ConfP-111	97.7	YES	TP168	3.7
583104	Month 9	SP146	0.122	4.5	POSITIVE	ConfP-111	94.0	YES	TP168	2.7
583104	Month 12	SP146	0.099	3.2	POSITIVE	ConfP-111	87.9	YES	TP168	2.7
583104	Month 18	SP146	0.648	33.7	POSITIVE	ConfP-111	98.0	YES	TP168	3.7
583104	Month 24	SP146	0.326	15.8	POSITIVE	ConfP-111	95.0	YES	TP168	3.7
583105	Baseline	SP147	0.045	0.1	Negative					
583105	Month 1	SP147	0.675	34.0	POSITIVE	ConfP-111	99.6	YES	TP169	3.7
583105	Month 3	SP147	2.489	131.7	POSITIVE	ConfP-111	99.7	YES	TP169	4.7
583105	Month 6	SP147	1.752	92.0	POSITIVE	ConfP-111	99.8	YES	TP169	3.7
583105	Month 9	SP147	1.047	54.0	POSITIVE	ConfP-112	99.3	YES	TP170	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
583105	Month 12	SP147	0.932	47.8	POSITIVE	ConfP-112	99.5	YES	TP170	3.7
583105	Month 18	SP147	0.493	24.2	POSITIVE	ConfP-112	99.3	YES	TP170	3.7
583105	Month 24	SP147	0.330	15.4	POSITIVE	ConfP-112	98.2	YES	TP170	2.7
583601	Baseline	SP147	0.047	0.2	Negative					
583601	Month 1	SP147	0.277	12.5	POSITIVE	ConfP-112	95.1	YES	TP170	2.7
583601	Month 3	SP147	1.553	81.3	POSITIVE	ConfP-112	98.1	YES	TP170	3.7
583601	Month 6	SP147	1.006	51.8	POSITIVE	ConfP-112	97.7	YES	TP171	3.7
583601	Month 9	SP148	0.675	33.4	POSITIVE	ConfP-113	97.8	YES	TP172	2.7
583601	Month 12	SP148	0.298	13.5	POSITIVE	ConfP-113	95.5	YES	TP172	2.7
583601	Month 18	SP148	0.208	8.8	POSITIVE	ConfP-113	94.7	YES	TP172	2.7
583601	Month 24	SP148	0.119	4.1	POSITIVE	ConfP-113	86.4	YES	TP172	2.7
583603	Baseline	SP148	0.047	0.3	Negative					
583603	Month 1	SP148	0.098	3.0	POSITIVE	ConfP-112	93.0	YES	TP171	2.7
583603	Month 3	SP148	0.133	4.8	POSITIVE	ConfP-112	97.2	YES	TP171	2.7
583603	Month 6	SP148	0.119	4.1	POSITIVE	ConfP-112	97.6	YES	TP171	2.7
583603	Month 9	SP148	0.175	7.1	POSITIVE	ConfP-112	98.9	YES	TP171	2.7
583603	Month 12	SP148	0.253	11.2	POSITIVE	ConfP-112	99.3	YES	TP171	2.7
583603	Month 18	SP148	0.222	9.5	POSITIVE	ConfP-112	98.7	YES	TP172	2.7
583603	Month 24	SP148	0.185	7.6	POSITIVE	ConfP-113	98.6	YES	TP172	2.7
583604	Baseline	SP149	0.044	0.0	Negative					
583604	Month 1	SP149	0.288	16.7	POSITIVE	ConfP-113	98.1	YES	TP173	2.7
583604	Month 3	SP149	0.566	35.8	POSITIVE	ConfP-113	99.4	YES	TP173	3.7
583604	Month 6	SP149	0.441	27.2	POSITIVE	ConfP-113	98.9	YES	TP173	2.7
583604	Month 9	SP149	0.222	12.2	POSITIVE	ConfP-113	98.0	YES	TP173	2.7
583604	Month 12	SP149	0.224	12.3	POSITIVE	ConfP-113	97.0	YES	TP173	2.7
583604	Month 18	SP149	0.091	3.2	POSITIVE	ConfP-113	96.2	YES	TP174	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
583604	Month 24	SP149	0.137	6.4	POSITIVE	ConfP-113	98.3	YES	TP174	2.7
583701	Baseline	SP32	0.047	0.1	Negative					
583701	Month 1	SP32	0.062	1.2	Negative					
583701	Month 3	SP32	0.327	20.0	POSITIVE	ConfP-4	100.0	YES	TP12	2.7
583701	Month 6	SP32	0.075	2.1	POSITIVE	ConfP-26	96.9	YES	TP253	2.7
583701	Month 9	SP32	0.188	10.1	POSITIVE	ConfP-26	99.2	YES	TP254	2.7
583701	Month 12	SP32	0.074	2.1	POSITIVE	ConfP-26	85.0	YES	TP254	2.7
583701	Month 18	SP32	0.315	19.1	POSITIVE	ConfP-27	99.7	YES	TP254	2.7
583701	Month 24	SP32	0.115	5.0	POSITIVE	ConfP-27	98.4	YES	TP254	2.7
583703	Baseline	SP149	0.045	0.1	Negative					
583703	Month 1	SP149	0.112	4.7	POSITIVE	ConfP-114	97.6	YES	TP174	2.7
583703	Month 3	SP149	0.276	15.9	POSITIVE	ConfP-114	99.2	YES	TP174	2.7
583703	Month 6	SP149	0.149	7.2	POSITIVE	ConfP-114	99.2	YES	TP174	2.7
583703	Month 9	SP150	0.206	9.9	POSITIVE	ConfP-114	97.9	YES	TP176	3.7
583703	Month 12	SP150	0.115	4.3	POSITIVE	ConfP-114	96.3	YES	TP176	2.7
583703	Month 18	SP150	0.115	4.3	POSITIVE	ConfP-114	97.4	YES	TP176	2.7
583703	Month 24	SP150	0.089	2.8	POSITIVE	ConfP-115	93.0	YES	TP176	2.7
583706	Baseline	SP150	0.045	0.1	Negative					
583706	Month 1	SP150	0.374	20.2	POSITIVE	ConfP-114	97.4	YES	TP174	2.7
583706	Month 3	SP150	0.545	30.7	POSITIVE	ConfP-114	98.4	YES	TP175	3.7
583706	Month 6	SP150	0.389	21.1	POSITIVE	ConfP-114	98.1	YES	TP175	3.7
583706	Month 9	SP150	0.239	11.9	POSITIVE	ConfP-114	97.4	YES	TP175	4.7
583706	Month 12	SP150	0.389	21.1	POSITIVE	ConfP-114	98.4	YES	TP175	3.7
583706	Month 18	SP150	0.251	12.7	POSITIVE	ConfP-114	97.2	YES	TP175	3.7
583706	Month 24	SP150	0.255	12.9	POSITIVE	ConfP-114	97.9	YES	TP175	3.7
583708	Baseline	SP151	0.067	1.4	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
583708	Month 1	SP151	1.316	71.4	POSITIVE	ConfP-115	98.9	YES	TP176	3.7
583708	Month 3	SP151	0.923	49.4	POSITIVE	ConfP-115	99.0	YES	TP176	3.7
583708	Month 6	SP151	1.062	57.1	POSITIVE	ConfP-115	99.3	YES	TP177	3.7
583708	Month 9	SP151	0.246	11.4	POSITIVE	ConfP-115	96.8	YES	TP177	2.7
583708	Month 12	SP151	0.320	15.6	POSITIVE	ConfP-115	98.1	YES	TP177	2.7
583708	Month 18	SP151	0.691	36.4	POSITIVE	ConfP-115	99.0	YES	TP177	3.7
583708	Month 24	SP151	0.840	44.7	POSITIVE	ConfP-115	98.8	YES	TP177	3.7
600902	Baseline	SP33	0.044	0.0	Negative					
600902	Month 1	SP33	0.123	4.8	POSITIVE	ConfP-27	98.8	YES	TP254	2.7
600902	Month 3	SP33	1.054	62.0	POSITIVE	ConfP-4	100.0	YES	TP12	3.7
600902	Month 6	SP33	0.370	20.0	POSITIVE	ConfP-27	99.2	YES	TP254	2.7
600902	Month 9	SP33	0.318	16.8	POSITIVE	ConfP-27	99.5	YES	TP255	3.7
600902	Month 12	SP33	0.200	9.6	POSITIVE	ConfP-27	99.4	YES	TP255	2.7
600902	Month 18	SP33	0.289	15.0	POSITIVE	ConfP-27	99.2	YES	TP255	2.7
600902	Month 24	SP33	0.210	10.2	POSITIVE	ConfP-27	99.0	YES	TP255	2.7
600904	Baseline	SP33	0.043	0.0	Negative					
600904	Month 1	SP33	0.445	24.6	POSITIVE	ConfP-27	99.4	YES	TP255	3.7
600904	Month 3	SP33	1.101	64.9	POSITIVE	ConfP-4	99.9	YES	TP12	3.7
600904	Month 6	SP33	0.873	50.9	POSITIVE	ConfP-27	99.3	YES	TP255	3.7
600904	Month 9	SP34	0.604	35.6	POSITIVE	ConfP-27	99.3	YES	TP256	3.7
600904	Month 12	SP34	0.452	26.0	POSITIVE	ConfP-27	99.2	YES	TP256	3.7
600904	Month 18	SP34	0.359	20.1	POSITIVE	ConfP-27	98.7	YES	TP256	3.7
600904	Month 24	SP34	0.370	20.8	POSITIVE	ConfP-28	99.7	YES	TP256	3.7
600905	Baseline	SP34	0.043	0.0	Negative					
600905	Month 1	SP34	1.080	65.9	POSITIVE	ConfP-28	99.7	YES	TP256	4.7
600905	Month 3	SP34	1.300	79.9	POSITIVE	ConfP-4	100.0	YES	TP13	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
600905	Month 6	SP34	0.324	17.9	POSITIVE	ConfP-28	99.0	YES	TP256	3.7
600905	Month 9	SP34	0.314	17.2	POSITIVE	ConfP-28	98.6	YES	TP257	3.7
600905	Month 12	SP34	0.279	15.0	POSITIVE	ConfP-28	98.7	YES	TP257	2.7
600905	Month 18	SP34	0.597	35.2	POSITIVE	ConfP-28	96.7	YES	TP257	3.7
600905	Month 24	SP34	0.129	5.5	POSITIVE	ConfP-28	93.7	YES	TP257	2.7
600906	Baseline	SP35	0.052	0.6	Negative					
600906	Month 1	SP35	0.111	4.1	POSITIVE	ConfP-28	99.2	YES	TP257	3.7
600906	Month 3	SP35	0.904	51.4	POSITIVE	ConfP-4	99.3	YES	TP13	3.7
600906	Month 6	SP35	0.519	28.4	POSITIVE	ConfP-28	99.2	YES	TP257	3.7
600906	Month 9	SP35	0.302	15.5	POSITIVE	ConfP-28	99.2	YES	TP258	2.7
600906	Month 12	SP35	0.266	13.4	POSITIVE	ConfP-28	99.2	YES	TP258	2.7
600906	Month 18	SP35	0.293	15.0	POSITIVE	ConfP-28	99.4	YES	TP258	3.7
600906	Month 24	SP35	0.241	11.9	POSITIVE	ConfP-28	99.3	YES	TP258	2.7
600909	Baseline	SP35	0.043	0.1	Negative					
600909	Month 1	SP35	0.838	47.5	POSITIVE	ConfP-4	100.0	YES	TP13	3.7
600909	Month 3	SP35	0.152	6.6	POSITIVE	ConfP-29	98.9	YES	TP258	2.7
600909	Month 6	SP35	0.204	9.7	POSITIVE	ConfP-29	98.1	YES	TP258	2.7
600909	Month 9	SP36	0.201	9.1	POSITIVE	ConfP-29	99.5	YES	TP259	2.7
600909	Month 12	SP36	0.117	4.3	POSITIVE	ConfP-29	99.2	YES	TP259	2.7
600909	Month 18	SP36	0.344	17.3	POSITIVE	ConfP-29	99.7	YES	TP259	3.7
600909	Month 24	SP36	0.121	4.5	POSITIVE	ConfP-29	99.3	YES	TP259	2.7
600914	Baseline	SP36	0.174	7.5	POSITIVE	ConfP-29	12.4	No		
600914	Month 1	SP36	0.322	16.0	POSITIVE	ConfP-29	63.8	YES	TP259	2.7
600914	Month 3	SP36	0.403	20.7	POSITIVE	ConfP-4	100.0	YES	TP13	2.7
600914	Month 6	SP36	0.225	10.5	POSITIVE	ConfP-29	61.1	YES	TP260	2.7
600914	Month 9	SP36	0.198	8.9	POSITIVE	ConfP-29	56.8	YES	TP260	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
600914	Month 12	SP36	0.217	10.0	POSITIVE	ConfP-29	58.5	YES	TP260	2.7
600914	Month 18	SP36	0.283	13.8	POSITIVE	ConfP-29	60.2	YES	TP260	2.7
600914	Month 24	SP36	0.302	14.9	POSITIVE	ConfP-29	72.6	YES	TP260	2.7
600915	Baseline	SP37	0.044	0.1	Negative					
600915	Month 1	SP37	0.294	22.4	POSITIVE	ConfP-30	99.5	YES	TP260	3.7
600915	Month 3	SP37	0.957	81.5	POSITIVE	ConfP-5	100.0	YES	TP1	3.7
600915	Month 6	SP37	0.146	9.2	POSITIVE	ConfP-30	99.6	YES	TP261	2.7
600915	Month 9	SP37	0.472	38.3	POSITIVE	ConfP-30	99.7	YES	TP261	3.7
600915	Month 12	SP37	0.493	40.1	POSITIVE	ConfP-30	99.8	YES	TP261	3.7
600915	Month 18	SP37	0.141	8.7	POSITIVE	ConfP-30	99.6	YES	TP261	2.7
600915	Month 24	SP37	0.182	12.4	POSITIVE	ConfP-30	99.3	YES	TP261	2.7
600919	Baseline	SP37	0.056	1.2	Negative					
600919	Month 1	SP37	0.268	20.1	POSITIVE	ConfP-30	76.7	YES	TP261	3.7
600919	Month 3	SP37	1.507	130.6	POSITIVE	ConfP-5	99.3	YES	TP1	3.7
600919	Month 6	SP37	0.454	36.7	POSITIVE	ConfP-30	88.2	YES	TP262	3.7
600919	Month 9	SP38	0.456	34.8	POSITIVE	ConfP-30	91.8	YES	TP262	2.7
600919	Month 12	SP38	0.677	53.4	POSITIVE	ConfP-30	95.1	YES	TP262	3.7
600919	Month 18	SP38	0.230	15.8	POSITIVE	ConfP-30	89.0	YES	TP262	2.7
600919	Month 24	SP38	0.227	15.5	POSITIVE	ConfP-30	91.6	YES	TP262	2.7
600923	Baseline	ConfP-147	0.082	0.3	Negative					
600923	Baseline	ConfP-147	0.086	0.6	Negative					
600923	Month 1	SP194	0.932	34.7	POSITIVE	ConfP-143	99.3	YES	TP311	2.7
600923	Month 3	SP194	2.378	92.1	POSITIVE	ConfP-147	99.5	YES	TP311	3.7
600923	Month 6	SP194	0.934	34.7	POSITIVE	ConfP-143	99.1	YES	TP311	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
600923	Month 9					No sample received				
600923	Month 12	SP194	0.324	10.5	POSITIVE	ConfP-143	99.4	YES	TP311	2.7
600923	Month 18	SP194	0.359	11.9	POSITIVE	ConfP-143	100.0	YES	TP311	2.7
600923	Month 24	SP196	1.780	71.0	POSITIVE	ConfP-143	99.5	YES	TP311	3.7
600929	Baseline	SP38	0.045	0.2	Negative					
600929	Month 1	SP38	0.205	13.6	POSITIVE	ConfP-30	97.2	YES	TP262	2.7
600929	Month 3	SP38	1.439	117.6	POSITIVE	ConfP-31	93.8	YES	TP263	3.7
600929	Month 6	SP38	1.494	122.2	POSITIVE	ConfP-5	96.7	YES	TP1	3.7
600929	Month 9	SP38	0.705	55.8	POSITIVE	ConfP-31	94.7	YES	TP263	3.7
600929	Month 12	SP38	0.855	68.4	POSITIVE	ConfP-31	95.4	YES	TP263	3.7
600929	Month 18	SP38	0.717	56.8	POSITIVE	ConfP-31	80.9	YES	TP263	3.7
600929	Month 24	SP38	1.035	83.6	POSITIVE	ConfP-31	66.8	YES	TP263	3.7
600933	Baseline	SP39	0.044	0.0	Negative					
600933	Month 1	SP39	0.046	0.0	Negative					
600933	Month 3	SP39	0.174	10.4	POSITIVE	ConfP-31	99.7	YES	TP263	2.7
600933	Month 6	SP39	0.204	12.8	POSITIVE	ConfP-5	100.0	YES	TP1	2.7
600933	Month 9	SP39	0.097	4.1	POSITIVE	ConfP-31	99.0	YES	TP264	2.7
600933	Month 12	SP39	0.072	2.1	POSITIVE	ConfP-31	98.5	YES	TP264	2.7
600933	Month 18	SP39	0.053	0.6	Negative					
600933	Month 24	SP39	0.085	3.2	POSITIVE	ConfP-31	100.0	YES	TP264	2.7
601002	Baseline	SP39	0.044	0.0	Negative					
601002	Month 1	SP39	0.794	60.8	POSITIVE	ConfP-31	99.6	YES	TP264	3.7
601002	Month 3	SP39	0.903	69.7	POSITIVE	ConfP-5	98.8	YES	TP1	3.7
601002	Month 6	SP39	0.403	29.0	POSITIVE	ConfP-31	98.9	YES	TP264	2.7
601002	Month 9	SP40	0.308	21.7	POSITIVE	ConfP-31	98.7	YES	TP264	2.7
601002	Month 12	SP40	0.312	22.0	POSITIVE	ConfP-31	99.1	YES	TP265	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601002	Month 18	SP40	0.293	20.5	POSITIVE	ConfP-32	98.8	YES	TP265	2.7
601002	Month 24	SP40	0.237	15.9	POSITIVE	ConfP-32	98.8	YES	TP265	2.7
601003	Baseline	SP40	0.050	0.4	Negative					
601003	Month 1	SP40	0.253	17.2	POSITIVE	ConfP-5	100.0	YES	TP1	2.7
601003	Month 3	SP40	0.221	14.5	POSITIVE	ConfP-32	99.1	YES	TP265	2.7
601003	Month 6	SP40	0.077	2.6	POSITIVE	ConfP-32	95.3	YES	TP265	2.7
601003	Month 9	SP40	0.096	4.2	POSITIVE	ConfP-32	97.3	YES	TP265	2.7
601003	Month 12	SP40	0.142	8.0	POSITIVE	ConfP-32	97.8	YES	TP266	2.7
601003	Month 18	SP40	0.108	5.2	POSITIVE	ConfP-32	98.4	YES	TP266	2.7
601003	Month 24	SP40	0.103	4.8	POSITIVE	ConfP-32	98.9	YES	TP266	2.7
601004	Baseline	SP41	0.049	0.2	Negative					
601004	Month 1	SP41	1.168	53.0	POSITIVE	ConfP-32	99.8	YES	TP266	3.7
601004	Month 3	SP41	1.892	87.1	POSITIVE	ConfP-5	99.6	YES	TP2	3.7
601004	Month 6	SP41	1.129	51.2	POSITIVE	ConfP-32	99.9	YES	TP266	2.7
601004	Month 9	SP41	1.128	51.1	POSITIVE	ConfP-32	99.6	YES	TP266	2.7
601004	Month 12					No sample received				
601004	Month 18	SP41	0.767	34.1	POSITIVE	ConfP-32	99.8	YES	TP267	2.7
601004	Month 24	SP41	0.245	9.5	POSITIVE	ConfP-32	98.9	YES	TP267	2.7
601005	Baseline	SP41	0.052	0.4	Negative					
601005	Month 1	SP41	1.343	61.2	POSITIVE	ConfP-33	98.3	YES	TP267	3.7
601005	Month 3	SP41	1.341	61.2	POSITIVE	ConfP-5	100.0	YES	TP2	3.7
601005	Month 6	SP41	0.357	14.8	POSITIVE	ConfP-33	98.7	YES	TP267	2.7
601005	Month 9	SP42	0.359	14.4	POSITIVE	ConfP-40	97.8	YES	TP267	2.7
601005	Month 12	SP42	0.428	17.7	POSITIVE	ConfP-33	99.2	YES	TP267	2.7
601005	Month 18	SP42	0.427	17.7	POSITIVE	ConfP-33	98.8	YES	TP268	2.7
601005	Month 24	SP42	0.216	7.6	POSITIVE	ConfP-33	93.5	YES	TP268	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601008	Baseline	SP42	0.065	0.3	Negative					
601008	Month 1	SP42	0.827	36.8	POSITIVE	ConfP-33	99.0	YES	TP268	2.7
601008	Month 3	SP42	2.219	103.4	POSITIVE	ConfP-5	99.8	YES	TP2	3.7
601008	Month 6	SP42	1.591	73.4	POSITIVE	ConfP-33	99.5	YES	TP268	3.7
601008	Month 9	SP42	1.477	67.9	POSITIVE	ConfP-33	99.7	YES	TP268	3.7
601008	Month 12	SP42	1.320	60.4	POSITIVE	ConfP-33	99.8	YES	TP268	3.7
601008	Month 18	SP42	1.361	62.4	POSITIVE	ConfP-33	99.7	YES	TP269	3.7
601008	Month 24	SP42	1.909	88.6	POSITIVE	ConfP-33	99.6	YES	TP269	3.7
601009	Baseline	SP43	0.047	0.2	Negative					
601009	Month 1	SP43	0.273	12.8	POSITIVE	ConfP-33	99.2	YES	TP269	2.7
601009	Month 3	SP43	1.941	106.0	POSITIVE	ConfP-5	99.9	YES	TP2	3.7
601009	Month 6	SP43	0.881	46.8	POSITIVE	ConfP-34	100.0	YES	TP269	2.7
601009	Month 9	SP43	0.362	17.8	POSITIVE	ConfP-34	100.0	YES	TP269	2.7
601009	Month 12	SP43	0.265	12.3	POSITIVE	ConfP-34	100.0	YES	TP269	2.7
601009	Month 18	SP43	0.215	9.6	POSITIVE	ConfP-34	99.5	YES	TP270	2.7
601009	Month 24	SP43	0.300	14.3	POSITIVE	ConfP-34	100.0	YES	TP270	2.7
601011	Baseline	SP43	0.056	0.7	Negative					
601011	Month 1	SP43	0.135	5.1	POSITIVE	ConfP-34	95.9	YES	TP270	2.7
601011	Month 3	SP43	1.281	69.1	POSITIVE	ConfP-5	99.6	YES	TP2	3.7
601011	Month 6	SP43	1.022	54.6	POSITIVE	ConfP-34	99.1	YES	TP270	3.7
601011	Month 9	SP44	0.707	39.3	POSITIVE	ConfP-34	99.4	YES	TP270	2.7
601011	Month 12	SP44	0.416	22.0	POSITIVE	ConfP-34	100.0	YES	TP270	2.7
601011	Month 18	SP44	0.361	18.8	POSITIVE	ConfP-34	98.8	YES	TP271	2.7
601011	Month 24	SP44	0.341	17.6	POSITIVE	ConfP-34	98.0	YES	TP271	2.7
601013	Baseline	SP44	0.050	0.3	Negative					
601013	Month 1	SP44	0.275	13.7	POSITIVE	ConfP-34	98.2	YES	TP271	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601013	Month 3	SP44	0.699	38.8	POSITIVE	ConfP-34	100.0	YES	TP271	2.7
601013	Month 6	SP44	0.970	54.9	POSITIVE	ConfP-5	99.7	YES	TP2	2.7
601013	Month 9	SP44	0.752	42.0	POSITIVE	ConfP-35	99.4	YES	TP271	2.7
601013	Month 12	SP44	0.396	20.8	POSITIVE	ConfP-35	99.4	YES	TP271	2.7
601013	Month 18	SP44	0.947	53.6	POSITIVE	ConfP-35	99.5	YES	TP272	2.7
601013	Month 24	SP44	0.539	29.3	POSITIVE	ConfP-35	99.8	YES	TP272	2.7
601015	Baseline	SP45	0.045	0.0	Negative					
601015	Month 1	SP45	0.409	18.0	POSITIVE	ConfP-35	99.5	YES	TP272	3.7
601015	Month 3	SP45	2.180	105.4	POSITIVE	ConfP-5	99.7	YES	TP3	3.7
601015	Month 6	SP45	1.342	64.0	POSITIVE	ConfP-35	98.2	YES	TP272	3.7
601015	Month 9	SP45	0.975	45.9	POSITIVE	ConfP-35	98.2	YES	TP272	3.7
601015	Month 12	SP45	0.478	21.4	POSITIVE	ConfP-35	97.8	YES	TP272	2.7
601015	Month 18	SP45	0.552	25.0	POSITIVE	ConfP-35	98.5	YES	TP273	2.7
601015	Month 24	SP45	0.270	11.1	POSITIVE	ConfP-35	97.7	YES	TP273	2.7
601017	Baseline	SP151	0.049	0.4	Negative					
601017	Month 1	SP151	0.165	6.9	POSITIVE	ConfP-115	90.1	YES	TP177	2.7
601017	Month 3	SP151	1.888	103.4	POSITIVE	ConfP-115	98.9	YES	TP178	3.7
601017	Month 6	SP151	1.004	53.9	POSITIVE	ConfP-115	97.8	YES	TP178	3.7
601017	Month 9	SP152	1.108	59.6	POSITIVE	ConfP-116	95.7	YES	TP179	3.7
601017	Month 12	SP152	2.003	109.7	POSITIVE	ConfP-116	98.0	YES	TP179	4.7
601017	Month 18	SP152	0.403	20.1	POSITIVE	ConfP-116	91.0	YES	TP179	3.7
601017	Month 24	SP152	0.183	7.8	POSITIVE	ConfP-116	80.5	YES	TP179	2.7
601019	Baseline	SP152	0.056	0.7	Negative					
601019	Month 1	SP152	0.044	0.1	Negative					
601019	Month 3	SP152	1.269	68.6	POSITIVE	ConfP-115	99.4	YES	TP178	3.7
601019	Month 6	SP152	0.677	35.5	POSITIVE	ConfP-115	98.1	YES	TP178	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601019	Month 9	SP152	0.512	26.2	POSITIVE	ConfP-116	98.7	YES	TP178	3.7
601019	Month 12	SP152	0.566	29.3	POSITIVE	ConfP-116	99.5	YES	TP178	3.7
601019	Month 18	SP152	0.317	15.3	POSITIVE	ConfP-116	99.1	YES	TP179	3.7
601019	Month 24	SP152	0.488	24.9	POSITIVE	ConfP-116	98.8	YES	TP179	3.7
601020	Baseline	SP153	0.046	0.2	Negative					
601020	Month 1	SP153	0.113	5.0	POSITIVE	ConfP-116	86.0	YES	TP180	2.7
601020	Month 3	SP153	1.494	103.3	POSITIVE	ConfP-116	98.9	YES	TP180	3.7
601020	Month 6	SP153	0.243	14.2	POSITIVE	ConfP-116	93.3	YES	TP180	3.7
601020	Month 9	SP153	0.265	15.8	POSITIVE	ConfP-116	96.9	YES	TP180	2.7
601020	Month 12	SP153	0.249	14.7	POSITIVE	ConfP-116	96.0	YES	TP180	2.7
601020	Month 18	SP153	0.180	9.8	POSITIVE	ConfP-117	92.1	YES	TP180	2.7
601020	Month 24	SP153	0.145	7.3	POSITIVE	ConfP-117	87.2	YES	TP181	2.7
601022	Baseline	SP153	0.048	0.4	Negative					
601022	Month 1	SP153	0.319	19.6	POSITIVE	ConfP-117	97.0	YES	TP181	3.7
601022	Month 3	SP153	1.013	69.0	POSITIVE	ConfP-117	99.0	YES	TP181	3.7
601022	Month 6	SP153	0.790	53.2	POSITIVE	ConfP-117	97.5	YES	TP181	3.7
601022	Month 9	SP154	0.998	70.9	POSITIVE	ConfP-118	98.7	YES	TP183	3.7
601022	Month 12	SP154	1.401	100.8	POSITIVE	ConfP-118	98.9	YES	TP183	3.7
601022	Month 18	SP154	1.831	132.7	POSITIVE	ConfP-118	99.2	YES	TP183	4.7
601022	Month 24	SP154	1.573	113.6	POSITIVE	ConfP-118	98.6	YES	TP183	3.7
601023	Baseline	SP154	0.091	3.7	POSITIVE	ConfP-117	90.0	YES	TP181	2.7
601023	Month 1	SP154	1.359	97.7	POSITIVE	ConfP-117	99.5	YES	TP181	3.7
601023	Month 3	SP154	1.683	121.7	POSITIVE	ConfP-117	99.5	YES	TP182	4.7
601023	Month 6	SP154	1.603	115.8	POSITIVE	ConfP-117	99.5	YES	TP182	4.7
601023	Month 9	SP154	1.304	93.6	POSITIVE	ConfP-117	99.2	YES	TP182	3.7
601023	Month 12	SP154	1.170	83.7	POSITIVE	ConfP-117	98.4	YES	TP182	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601023	Month 18	SP154	1.218	87.2	POSITIVE	ConfP-117	96.4	YES	TP182	3.7
601023	Month 24	SP154	1.084	77.3	POSITIVE	ConfP-117	95.0	YES	TP182	3.7
601025	Baseline	SP155	0.049	0.5	Negative					
601025	Month 1	SP155	1.110	71.7	POSITIVE	ConfP-118	98.9	YES	TP183	3.7
601025	Month 3	SP155	2.021	132.8	POSITIVE	ConfP-118	99.4	YES	TP183	4.7
601025	Month 6	SP155	0.902	57.7	POSITIVE	ConfP-118	98.7	YES	TP184	3.7
601025	Month 9	SP155	0.467	28.5	POSITIVE	ConfP-118	97.9	YES	TP184	2.7
601025	Month 12	SP155	0.409	24.6	POSITIVE	ConfP-118	98.0	YES	TP184	2.7
601025	Month 18	SP155	0.668	42.0	POSITIVE	ConfP-118	99.0	YES	TP184	3.7
601025	Month 24	SP155	1.253	81.3	POSITIVE	ConfP-118	98.2	YES	TP184	3.7
601027	Baseline	SP155	0.046	0.3	Negative					
601027	Month 1	SP155	0.714	45.1	POSITIVE	ConfP-118	98.9	YES	TP184	3.7
601027	Month 3	SP155	0.496	30.5	POSITIVE	ConfP-118	99.0	YES	TP185	3.7
601027	Month 6	SP155	0.345	20.3	POSITIVE	ConfP-119	97.8	YES	TP185	2.7
601027	Month 9	SP156	0.147	6.7	POSITIVE	ConfP-119	90.8	YES	TP186	2.7
601027	Month 12	SP156	0.170	8.4	POSITIVE	ConfP-119	97.9	YES	TP186	2.7
601027	Month 18	SP156	0.092	2.8	POSITIVE	ConfP-119	94.2	YES	TP186	2.7
601027	Month 24	SP156	0.119	4.8	POSITIVE	ConfP-119	94.9	YES	TP187	2.7
601027	TERM									
601027	OL/ET OL	SP156	0.055	0.2	Negative					
601030	Baseline	SP192	0.080	0.3	Negative					
601030	Month 1	SP192	0.559	21.1	POSITIVE	ConfP-141	98.4	YES	TP309	2.7
601030	Month 3	SP192	1.213	49.5	POSITIVE	ConfP-141	99.6	YES	TP309	3.7
601030	Month 6					No sample received				
601030	Month 9	SP192	0.349	11.9	POSITIVE	ConfP-141	99.4	YES	TP309	2.7
601030	Month 12	SP192	0.405	14.4	POSITIVE	ConfP-141	100.0	YES	TP309	2.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601030	Month 18	SP192	0.169	4.1	POSITIVE	ConfP-141	97.8	YES	TP309	2.7
601030	Month 24	SP192	0.277	8.8	POSITIVE	ConfP-141	98.9	YES	TP309	2.7
601033	Baseline	SP156	0.069	1.2	Negative					
601033	Month 1	SP156	0.374	22.8	POSITIVE	ConfP-119	97.2	YES	TP185	2.7
601033	Month 3	SP156	0.355	21.5	POSITIVE	ConfP-119	97.0	YES	TP185	2.7
601033	Month 6	SP156	0.221	12.0	POSITIVE	ConfP-119	95.4	YES	TP185	2.7
601033	Month 9	SP156	0.243	13.5	POSITIVE	ConfP-119	95.0	YES	TP185	2.7
601033	Month 12	SP156	0.163	7.9	POSITIVE	ConfP-119	92.9	YES	TP186	3.7
601033	Month 18	SP156	0.113	4.3	POSITIVE	ConfP-119	91.2	YES	TP186	3.7
601033	Month 24	SP156	0.153	7.2	POSITIVE	ConfP-119	90.7	YES	TP186	2.7
601034	Baseline	SP157	0.109	3.5	POSITIVE	ConfP-119	95.5	YES	TP187	2.7
601034	Month 1	SP157	1.117	58.0	POSITIVE	ConfP-120	98.5	YES	TP187	3.7
601034	Month 3	SP157	1.955	103.4	POSITIVE	ConfP-120	98.4	YES	TP187	3.7
601034	Month 6	SP157	1.303	68.1	POSITIVE	ConfP-120	98.3	YES	TP187	3.7
601034	Month 9	SP157	1.153	60.0	POSITIVE	ConfP-120	98.7	YES	TP187	3.7
601034	Month 12	SP157	1.326	69.3	POSITIVE	ConfP-120	99.3	YES	TP188	3.7
601034	Month 18	SP157	1.114	57.9	POSITIVE	ConfP-120	98.7	YES	TP188	3.7
601034	Month 24	SP157	0.862	44.2	POSITIVE	ConfP-120	99.0	YES	TP188	3.7
601205	Baseline	SP46	0.050	0.3	Negative					
601205	Month 1	SP46	0.064	1.0	Negative					
601205	Month 3	SP46	0.198	7.8	POSITIVE	ConfP-6	100.0	YES	TP3	2.7
601205	Month 6	SP46	0.096	2.6	POSITIVE	ConfP-36	97.6	YES	TP274	2.7
601205	Month 9	SP46	0.060	0.8	Negative					
601205	Month 12	SP46	0.051	0.3	Negative					
601205	Month 18	SP46	0.046	0.1	Negative					
601205	Month 24	SP46	0.045	0.0	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601208	Baseline	SP47	0.045	0.1	Negative					
601208	Month 1	SP47	1.225	59.8	POSITIVE	ConfP-36	99.5	YES	TP274	3.7
601208	Month 3	SP47	2.354	116.8	POSITIVE	ConfP-6	99.7	YES	TP3	3.7
601208	Month 6	SP47	0.632	29.8	POSITIVE	ConfP-36	99.6	YES	TP274	2.7
601208	Month 9	ConfP6	0.246	24.6	POSITIVE	ConfP-36	97.7	YES	TP274	2.7
601208	Month 12	SP47	1.359	66.5	POSITIVE	ConfP-36	99.6	YES	TP275	3.7
601208	Month 18	SP47	1.393	68.3	POSITIVE	ConfP-36	99.5	YES	TP275	3.7
601208	Month 24	SP47	0.804	38.5	POSITIVE	ConfP-36	99.3	YES	TP275	3.7
601209	Baseline	SP158	0.044	0.1	Negative					
601209	Month 1	SP158	1.019	52.6	POSITIVE	ConfP-120	98.5	YES	TP188	3.7
601209	Month 3	SP158	1.735	91.2	POSITIVE	ConfP-120	98.5	YES	TP189	3.7
601209	Month 6	SP158	0.629	31.6	POSITIVE	ConfP-120	96.9	YES	TP189	3.7
601209	Month 9	SP158	0.356	16.9	POSITIVE	ConfP-120	95.3	YES	TP189	2.7
601209	Month 12	SP158	0.557	27.7	POSITIVE	ConfP-121	96.6	YES	TP189	3.7
601209	Month 18	SP158	0.308	14.3	POSITIVE	ConfP-121	94.7	YES	TP189	2.7
601209	Month 24	SP158	0.330	15.5	POSITIVE	ConfP-121	94.2	YES	TP189	3.7
601212	Baseline	SP159	0.050	0.4	Negative					
601212	Month 1	SP159	1.749	92.0	POSITIVE	ConfP-121	99.3	YES	TP190	3.7
601212	Month 3	SP159	1.302	67.9	POSITIVE	ConfP-121	99.3	YES	TP190	3.7
601212	Month 6	SP159	0.779	39.7	POSITIVE	ConfP-121	98.8	YES	TP191	3.7
601212	Month 9	SP159	1.518	79.6	POSITIVE	ConfP-121	99.2	YES	TP191	3.7
601212	Month 12	SP159	1.061	54.9	POSITIVE	ConfP-121	99.1	YES	TP191	3.7
601212	Month 18	SP159	0.756	38.5	POSITIVE	ConfP-121	99.1	YES	TP191	3.7
601212	Month 24	SP159	1.228	63.9	POSITIVE	ConfP-122	99.0	YES	TP191	3.7
601301	Baseline	SP47	0.044	0.1	Negative					
601301	Month 1	SP47	0.196	7.7	POSITIVE	ConfP-36	99.4	YES	TP275	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601301	Month 3	SP47	2.516	125.0	POSITIVE	ConfP-6	99.6	YES	TP3	3.7
601301	Month 6	SP47	0.418	19.0	POSITIVE	ConfP-36	99.7	YES	TP275	3.7
601301	Month 9	SP48	0.303	13.8	POSITIVE	ConfP-36	99.5	YES	TP275	3.7
601301	Month 12	SP48	0.252	11.2	POSITIVE	ConfP-37	99.5	YES	TP276	2.7
601301	Month 18	SP48	0.205	8.7	POSITIVE	ConfP-37	99.7	YES	TP276	2.7
601301	Month 24	SP48	0.160	6.3	POSITIVE	ConfP-37	98.8	YES	TP276	2.7
601306	Baseline	SP159	0.045	0.2	Negative					
601306	Month 1	SP159	0.738	37.5	POSITIVE	ConfP-122	99.1	YES	TP191	3.7
601306	Month 3	SP159	0.777	39.6	POSITIVE	ConfP-122	99.1	YES	TP192	3.7
601306	Month 6	SP159	0.317	14.8	POSITIVE	ConfP-122	97.5	YES	TP192	2.7
601306	Month 9	SP160	0.328	15.8	POSITIVE	ConfP-122	97.5	YES	TP193	2.7
601306	Month 12	SP160	0.262	12.2	POSITIVE	ConfP-122	96.6	YES	TP193	2.7
601306	Month 18	SP160	0.343	16.6	POSITIVE	ConfP-123	95.1	YES	TP193	2.7
601306	Month 24	SP160	0.475	24.0	POSITIVE	ConfP-123	85.0	YES	TP194	3.7
601309	Baseline	SP160	0.048	0.3	Negative					
601309	Month 1	SP160	0.664	34.5	POSITIVE	ConfP-122	99.8	YES	TP192	2.7
601309	Month 3	SP160	0.499	25.3	POSITIVE	ConfP-122	99.8	YES	TP192	2.7
601309	Month 6	SP160	0.402	19.9	POSITIVE	ConfP-122	99.3	YES	TP192	2.7
601309	Month 9	SP160	0.322	15.5	POSITIVE	ConfP-122	99.3	YES	TP192	2.7
601309	Month 12	SP160	0.227	10.2	POSITIVE	ConfP-122	98.9	YES	TP193	2.7
601309	Month 18	SP160	0.113	3.9	POSITIVE	ConfP-122	99.2	YES	TP193	2.7
601309	Month 24	SP160	0.095	2.9	POSITIVE	ConfP-122	99.0	YES	TP193	2.7
601310	Baseline	SP161	0.043	0.0	Negative					
601310	Month 1	SP161	0.053	0.6	Negative					
601310	Month 3	SP161	0.183	8.2	POSITIVE	ConfP-123	97.9	YES	TP194	2.7
601310	Month 6	SP161	0.066	1.3	Negative					

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
601310	Month 9	SP161	0.098	3.2	POSITIVE	ConfP-123	93.2	YES	TP194	2.7
601310	Month 12	SP161	0.071	1.6	POSITIVE	ConfP-123	93.8	YES	TP194	2.7
601310	Month 18	SP161	0.084	2.4	POSITIVE	ConfP-123	95.1	YES	TP194	2.7
601310	Month 24	SP161	0.098	3.2	POSITIVE	ConfP-123	94.7	YES	TP194	2.7
811002	Baseline	SP48	0.046	0.3	Negative					
811002	Month 1	SP48	1.123	57.0	POSITIVE	ConfP-6	99.6	YES	TP3	3.7
811002	Month 3	SP48	0.048	0.4	Negative					
811002	Month 6	SP48	0.267	11.9	POSITIVE	ConfP-37	99.8	YES	TP276	3.7
811002	Month 9	SP48	0.107	3.5	POSITIVE	ConfP-37	99.7	YES	TP276	3.7
811002	Month 12	SP48	0.184	7.6	POSITIVE	ConfP-37	94.3	YES	TP276	3.7
811002	Month 18	SP48	0.146	5.6	POSITIVE	ConfP-37	98.9	YES	TP277	3.7
811002	Month 24	SP48	0.112	3.8	POSITIVE	ConfP-37	98.2	YES	TP277	2.7
811003	Baseline	SP49	0.045	0.2	Negative					
811003	Month 1	SP49	0.410	20.9	POSITIVE	ConfP-37	99.3	YES	TP277	3.7
811003	Month 3	SP49	1.168	64.0	POSITIVE	ConfP-6	99.3	YES	TP4	3.7
811003	Month 6	SP49	0.564	29.7	POSITIVE	ConfP-37	98.1	YES	TP277	3.7
811003	Month 9	SP49	0.448	23.1	POSITIVE	ConfP-37	97.3	YES	TP277	3.7
811003	Month 12	SP49	0.200	9.0	POSITIVE	ConfP-37	99.8	YES	TP277	2.7
811003	Month 18	SP49	0.175	7.6	POSITIVE	ConfP-37	84.5	YES	TP278	2.7
811003	Month 24	SP49	0.146	5.9	POSITIVE	ConfP-38	86.5	YES	TP278	2.7
811004	Baseline	SP49	0.050	0.5	Negative					
811004	Month 1	SP49	0.557	29.3	POSITIVE	ConfP-38	99.3	YES	TP278	3.7
811004	Month 3	SP49	0.762	40.9	POSITIVE	ConfP-6	99.5	YES	TP4	3.7
811004	Month 6	SP49	0.391	19.8	POSITIVE	ConfP-38	99.1	YES	TP278	3.7
811004	Month 9	SP50	0.354	17.5	POSITIVE	ConfP-38	99.1	YES	TP278	3.7
811004	Month 12	SP50	0.234	10.8	POSITIVE	ConfP-38	99.0	YES	TP278	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
811004	Month 18	SP50	0.347	17.1	POSITIVE	ConfP-38	98.6	YES	TP279	2.7
811004	Month 24	SP50	0.251	11.7	POSITIVE	ConfP-38	98.9	YES	TP279	2.7
811005	Baseline	SP50	0.046	0.2	Negative					
811005	Month 1	SP50	1.232	66.7	POSITIVE	ConfP-6	90.9	YES	TP4	3.7
811005	Month 3	SP50	1.104	59.6	POSITIVE	ConfP-38	97.7	YES	TP279	3.7
811005	Month 6	SP50	0.726	38.4	POSITIVE	ConfP-38	98.7	YES	TP279	4.7
811005	Month 9	SP50	0.269	12.7	POSITIVE	ConfP-38	99.0	YES	TP279	2.7
811005	Month 12	SP50	0.161	6.7	POSITIVE	ConfP-38	99.2	YES	TP280	2.7
811005	Month 18	SP50	0.106	3.6	POSITIVE	ConfP-38	98.3	YES	TP280	2.7
811005	Month 24	SP50	0.154	6.3	POSITIVE	ConfP-38	96.4	YES	TP280	2.7
811011	Baseline	SP161	0.043	0.0	Negative					
811011	Month 1	SP161	0.702	38.7	POSITIVE	ConfP-123	99.6	YES	TP195	3.7
811011	Month 3	SP161	0.451	23.9	POSITIVE	ConfP-123	99.7	YES	TP195	3.7
811011	Month 6	SP161	0.236	11.3	POSITIVE	ConfP-123	99.1	YES	TP195	3.7
811011	Month 9	SP162	0.170	7.7	POSITIVE	ConfP-124	90.0	YES	TP196	2.7
811011	Month 12	SP162	0.169	7.7	POSITIVE	ConfP-124	87.0	YES	TP196	2.7
811011	Month 18	SP162	0.145	6.2	POSITIVE	ConfP-124	76.7	YES	TP197	2.7
811011	Month 24	SP162	0.195	9.2	POSITIVE	ConfP-124	97.9	YES	TP197	2.7
811105	Baseline	SP184	0.047	0.2	Negative					
811105	Baseline	SP184	0.048	0.3	Negative					
811105	Month 1	SP162	1.048	60.4	POSITIVE	ConfP-123	99.3	YES	TP195	3.7
811105	Month 3	SP162	1.713	100.2	POSITIVE	ConfP-123	99.5	YES	TP195	4.7
811105	Month 6	SP162	1.329	77.2	POSITIVE	ConfP-133	98.9	YES	TP195	3.7
811105	Month 9	SP162	1.230	71.3	POSITIVE	ConfP-124	92.0	YES	TP196	3.7
811105	Month 12	SP162	1.175	68.0	POSITIVE	ConfP-133	98.9	YES	TP196	3.7
811105	Month 18	SP162	0.949	54.4	POSITIVE	ConfP-124	91.9	YES	TP196	3.7

Patient ID	Visit Name	Screening Plate#	Average OD	Screening RA%	Sample Positivity	Confirmation Plate#	Inhibition (%)	Confirmed Positivity (Yes/No)	Titration Plate#	Titer
811105	Month 24	SP162	0.826	47.1	POSITIVE	ConfP-124	96.9	YES	TP196	3.7
811106	Baseline	SP163	0.043	0.1	Negative					
811106	Month 1	SP163	1.136	60.6	POSITIVE	ConfP-124	98.7	YES	TP197	3.7
811106	Month 3	SP163	1.515	81.6	POSITIVE	ConfP-124	98.7	YES	TP197	4.7
811106	Month 6	SP163	0.666	34.6	POSITIVE	ConfP-124	97.2	YES	TP197	3.7
811106	Month 9	SP163	0.676	35.1	POSITIVE	ConfP-124	98.8	YES	TP197	3.7
811106	Month 12	SP163	0.838	44.1	POSITIVE	ConfP-125	99.3	YES	TP198	3.7
811106	Month 18	SP163	0.566	29.0	POSITIVE	ConfP-125	98.6	YES	TP198	3.7
811106	Month 24	SP163	0.422	21.0	POSITIVE	ConfP-125	98.5	YES	TP198	2.7
811107	Baseline	SP163	0.053	0.6	Negative					
811107	Month 1	SP163	0.801	42.0	POSITIVE	ConfP-125	99.0	YES	TP198	3.7
811107	Month 3	SP163	1.977	107.1	POSITIVE	ConfP-125	99.1	YES	TP198	4.7
811107	Month 6	SP163	1.602	86.4	POSITIVE	ConfP-125	99.0	YES	TP198	3.7
811107	Month 9	SP164	1.599	85.1	POSITIVE	ConfP-126	99.2	YES	TP200	3.7
811107	Month 12	SP164	1.510	80.3	POSITIVE	ConfP-126	99.4	YES	TP200	3.7
811107	Month 18	SP164	0.664	34.0	POSITIVE	ConfP-126	98.8	YES	TP200	3.7
811107	Month 24	SP164	0.777	40.2	POSITIVE	ConfP-126	98.8	YES	TP200	3.7
902201	Baseline	SP164	0.044	0.1	Negative					
902201	Month 1	SP164	0.433	21.3	POSITIVE	ConfP-125	98.9	YES	TP199	3.7
902201	Month 3	SP164	2.434	130.8	POSITIVE	ConfP-125	98.4	YES	TP199	4.7
902201	Month 6	SP164	2.343	125.8	POSITIVE	ConfP-125	99.3	YES	TP199	4.7
902201	Month 9	SP164	2.300	123.5	POSITIVE	ConfP-125	99.5	YES	TP199	4.7
902201	Month 12	SP164	2.001	107.1	POSITIVE	ConfP-125	99.5	YES	TP199	4.7
902201	Month 18	SP164	0.495	24.7	POSITIVE	ConfP-125	98.2	YES	TP199	3.7
902201	Month 24	SP164	0.612	31.1	POSITIVE	ConfP-125	99.1	YES	TP200	3.7

The average anti-GA IgG response (Screening RA%) of the GA treatment group at Baseline was 0.456818182 having a standard deviation of 0.683615214.

5 The average anti-GA IgG response (Screening RA%) of the GA treatment group at Month 1 was 34.7515625 having a standard deviation of 35.27291909.

The average anti-GA IgG response (Screening RA%) of the GA treatment group at Month 3 was 67.7229572 having a standard deviation of 38.6096852.

10 The average anti-GA IgG response (Screening RA%) of the GA treatment group at Month 6 was 39.69111969 having a standard deviation of 32.3192211.

The average anti-GA IgG response (Screening RA%) of the GA treatment group at Month 9 was 30.60694981 having a standard deviation of
15 29.94922134.

The average anti-GA IgG response (Screening RA%) of the GA treatment group at Month 12 was 28.94263566 having a standard deviation of 29.45298377.

The average anti-GA IgG response (Screening RA%) of the GA treatment
20 group at Month 18 was 24.8980695 having a standard deviation of 26.5184687.

The average anti-GA IgG response (Screening RA%) of the GA treatment group at Month 24 was 23.35938697 having a standard deviation of 26.93304872.

25 *Conclusion*

Serum samples were obtained at various time points during treatment from patients who were treated with 40mg/ml GA subcutaneous injection three times a week. The samples were tested for the presence of anti-GA IgG antibodies. In the screening tests, 1740 samples out of 1809
30 non-baseline samples were found to be positive and the positivity of

99.9% of the non-baseline samples was verified in the confirmatory test.

Every tested patients were confirmed positive for the presence of anti-GA IgG Abs. The total anti-GA IgG Abs titer was determined for
5 all confirmed samples.

The immunological response profile of the averaged anti-GA IgG response (mean RA% values) in 40mg/ml GA treatment group, was characterized by significant and fast increase of total anti-GA IgG Abs levels in the tested sera during the first treatment month followed
10 by relatively slower additional increase recorded at the 3 months time point. Total Anti-GA IgG levels decreased by month 6 of the treatment but did not reach the baseline level at month 24. See Figure 3.

DISCUSSION

Daily subcutaneous (sc) Copaxone® 20mg/mL is an approved drug product that contains the active ingredient, GA, the safety and efficacy of which are supported by over two decades of clinical research and over
5 a decade of post-marketing experience. Numerous studies have been conducted for the clinical effects of daily sc Copaxone® 20mg/mL, one of which is the antibody response to GA in MS patients (28).

A controlled study of 90 MS patients who were selected from the pilot clinical trial and treated with sc Copaxone® 20 mg/ml every day was
10 conducted and Ab levels were followed for 9 months. The total anti-GA specific antibody level peaked between about 3 and about 6 months, reaching at least 50 times baseline value. See Figure 1. The rate of increase of anti-GA specific antibody level between initiation of treatment and 1 month was greater than that between 1 month and 3
15 months. Decrease of anti-GA antibody level was usually detected by 6 months from initiation of treatment. After 6 months, the antibody level declined and remained low, although at a higher level than at baseline.

Consistent with the results of the 90 MS patients who were treated
20 with sc Copaxone® 20 mg/ml every day in the pilot trial and whose Ab levels were followed for 9 months, in another controlled clinical trial of 217 patients who were treated also with Copaxone® 20 mg/mL every day for 2 years, the anti-GA specific antibody level peaked between about 3 and about 6 months from initiation of treatment,
25 reaching at least 8 times baseline value. See Figure 2. By 6 months of treatment, however, decrease of anti-GA antibody level was observed. After 6 months, the antibody level declined and remained low, although at a somewhat higher level than at baseline. The antibodies were exclusively of the IgG subtype and not IgE or IgM,
30 and IgG1 levels were 2-3 fold higher than those of IgG2 at all the time points examined (28).

These results together suggest that MS patients develop an immunological response to daily sc administration of Copaxone 20 mg/mL, which is part of an overall immunomodulatory activity which

may be vital for the clinical efficacy of Copaxone 20 mg/mL.

Despite the clinical efficacy, a significant drawback to Copaxone® 20 mg/mL therapy is the requirement of daily injections, which can be inconvenient. Moreover, in all clinical trials, injection-site reactions were seen to be the most frequent adverse reactions and were reported by the majority of patients receiving Copaxone® 20 mg/mL. In controlled studies, the proportion of patients reporting these reactions, at least once, was higher following treatment with Copaxone® 20 mg/mL (70%) than placebo injections (37%). The most commonly reported injection-site reactions, which were more frequently reported in Copaxone® 20 mg/mL vs. placebo-treated patients, were erythema, pain, mass, pruritus, edema, inflammation and hypersensitivity.

However, several obstacles and limitations with potential approaches for addressing the drawbacks exist to current Copaxone® 20 mg/mL therapy. Subcutaneous drug delivery is limited, firstly, by the acceptable injection volume. Typically no more than 1 to 2 ml of solution is permitted (33). Secondly, the potential exists for drug degradation at the site of injection resulting in reduced bioavailability. Thirdly, based on the physiochemical properties of the drug, potent compounds may become locally trapped in the interstitial space which can lead to further localized irritation, precipitation of the drug and concentration-dependent adverse effects (34). Finally, due to the complex pharmacokinetic behavior of the drug, the efficacy and safety associated with any variation in the frequency of administration is unpredictable and requires empirical testing. For example, although controlled clinical trials have demonstrated the efficacy of IFN β -1b in the treatment of MS, patient compliance, efficacy and tolerability are affected by the dosage regimen used. Merely increasing the dose of IFN β -1b is insufficient to increase efficacy, the frequency of administration must also be increased (35).

The anti-GA specific antibody data of MS patients who were treated with Copaxone® 40mg/ml three times a week for a year (described in Example 1) is surprisingly consistent with the two clinical studies

discussed above, which were directed to 20mg/ml GA daily. The newly developed formulation of the active ingredient of GA, i.e. Copaxone® 40mg/ml three times a week, not only addresses the drawbacks of Copaxone® 20 mg/mL, e.g. by reducing frequency of injection and
5 potentially the Injection Related Adverse Events and Injection Site Reactions (38), but also does not compromise the antibody response observed after the administration of Copaxone® 20 mg/mL represented in Figures 1 and 2.

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What is claimed is:

1. A method of inducing anti-glatiramer acetate (GA) specific antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA specific antibodies in the blood or serum of the human subject
 - i) increases for up to about 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject;
 - ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
 - iii) peaks at about 3 or about 6 months or between about 3 and about 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
 - iv) is higher than baseline at least about 12 months after the initial 40 mg/ml dose of glatiramer acetate.
2. The method of claim 1, wherein the level of anti-GA specific antibodies in the blood or serum of the human subject increases for about 3 to about 6 months after the initial 40 mg/ml dose of glatiramer acetate.
3. The method of claim 1 or 2, wherein three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week are administered to the human subject for at least 18 months, and the level of anti-GA specific antibodies in the blood or serum of the human subject is higher than baseline about 18 months after the initial 40 mg/ml dose of glatiramer acetate.
4. The method of claim 3, wherein three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week are administered to the human subject for at least 24 months, and the level of anti-GA specific antibodies in the blood or serum of the human

subject is higher than baseline about 24 months after the initial 40 mg/ml dose of glatiramer acetate.

5. The method of any one of claims 1-4, wherein the anti-GA specific antibodies are other than IgM or IgE antibodies.
6. The method of any one of claims 1-5, wherein the level of anti-GA specific antibodies in the blood or serum of the human subject increases
 - i) to at least about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 67.5, about 70, about 75, about 80, about 25 to about 50, about 29 to about 106, about 29 to about 60, about 31 to about 60, about 35 to about 70, about 39 to about 71, about 50 to about 75, about 75 to about 80, or about 50 to about 80 RA% within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by an enzyme-linked immunosorbent assay (ELISA);
 - ii) by at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150, about 25.9 to about 975, or about 100 to about 200-fold increase in RA% over baseline within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA; or
 - iii) to at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150 or about 100 to about 200-fold over baseline.
7. A method of producing a glatiramer acetate response profile for a human subject afflicted with multiple sclerosis comprising the steps of:

- a) obtaining blood or serum samples periodically collected from a human subject afflicted with multiple sclerosis who is administered three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least about 12 or at least about 24 months after the initial 40 mg/ml dose of glatiramer acetate is administered;
 - b) assaying whether the level of anti-glatiramer acetate (GA) specific antibodies in the blood or serum of the human subject
 - i) increases for up to about 6 months after the initial 40 mg/ml dose of glatiramer acetate;
 - ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
 - iii) peaks at about 3 or about 6 months or between about 3 and about 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
 - iv) is higher than baseline about 12 and about 24 months after the initial 40 mg/ml dose of glatiramer acetate,
 - c) producing the glatiramer acetate response profile of the human subject comprising the level of anti-GA specific antibodies determined in step b).
8. The method of claim 7, comprising assaying whether the level of anti-GA specific antibodies in the blood or serum of the human subject increases for about 3 to about 6 months after the initial 40 mg/ml dose of glatiramer acetate.
9. The method of claim 7 or 8, further comprising assaying whether the anti-GA specific antibodies are other than IgM or IgE antibodies, and the glatiramer acetate response profile of the human subject produced in step c) identifies the anti-GA specific antibodies as other than IgM or IgG antibodies.

10. The method of claim 9, wherein the glatiramer acetate response profile is a written glatiramer acetate response profile report.
11. The method of any one of claims 7-10, wherein step b) comprises assaying whether the level of anti-GA specific antibodies in the blood or serum of the human subject increases
 - i) to at least about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 67.5, about 70, about 75, about 80, about 25 to about 50, about 29 to about 106, about 29 to about 60, about 31 to about 60, about 35 to about 70, about 39 to about 71, about 50 to about 75, about 75 to about 80, or about 50 to about 80 RA% within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by an enzyme-linked immunosorbent assay (ELISA);
 - ii) by at least an about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150, about 25.9 to about 975, or about 100 to about 200-fold increase in RA% over baseline within about 1, about 3, about 6, about 9, about 12, about 18, or about 24 months after the initial 40 mg/ml dose of glatiramer acetate, as measured by ELISA; or
 - iii) to at least about 5, about 10, about 15, about 20, about 25, about 30, about 35, about 40, about 45, about 50, about 55, about 60, about 65, about 70, about 75, about 80, about 85, about 90, about 95, about 100, about 110, about 120, about 130, about 140, about 150 or about 100 to about 200-fold over baseline.
12. The method of any one of claims 1-11, wherein the three subcutaneous injections are on three days each week selected from the group consisting of day 1, day 3 and day 5; day 1, day 3 and day 6; day 1, day 4 and day 6; day 2, day 4 and day 6; day

2, day 4 and day 7; 2, day 5 and day 7; and day 3, day 5 and day 7.

13. The method of any one of claims 1-12, wherein the glatiramer acetate is present in 1ml of a pharmaceutical composition in a prefilled syringe for self-administration by the human subject.

14. The method of any one of claims 1-13, wherein the pharmaceutical composition further comprises mannitol and has a pH in the range of 5.5 to 7.0.

15. The method of any one of claims 1-14, wherein the 40 mg/ml dose of glatiramer acetate is in a prefilled syringe containing 40mg of glatiramer acetate and 40mg mannitol.

16. The method of claim 15, wherein the prefilled syringe contains 1ml of an aqueous pharmaceutical solution of 40mg/ml of glatiramer acetate and 40mg/ml mannitol.

17. The method of claim 16, wherein the aqueous pharmaceutical solution

a) has a viscosity in the range of 2.0-3.5 cPa; or

b) has an osmolality in the range of 270-330 mosmol/Kg.

18. The method of claim 17, wherein the aqueous pharmaceutical solution

a) has a viscosity in the range of 2.2-3.0 cPa; or

b) has an osmolality in the range of 275-325 mosmol/Kg.

19. The method of any one of claims 1-16, wherein the 40 mg/ml dose of glatiramer acetate is an aqueous pharmaceutical solution comprising 40mg/ml glatiramer acetate and 40mg/ml mannitol, wherein the aqueous pharmaceutical solution

a) has a viscosity in the range of 2.0-3.5 cPa; or

b) has an osmolality in the range of 275-325 mosmol/Kg.

20. The method of claim 19, wherein the aqueous pharmaceutical solution has a viscosity in the range of 2.0-3.5 cPa.
21. The method of claim 19 or 20, wherein the aqueous pharmaceutical solution has a viscosity in the range of 2.61-2.92 cPa.
22. The method of any one of claims 19-21, wherein the aqueous pharmaceutical solution has an osmolality in the range of 275-325 mosmol/Kg.
23. The method of claim 22, wherein the aqueous pharmaceutical solution has an osmolality in the range of 300-303 mosmol/Kg.
24. The method of any one of claims 1-23, wherein the human subject is suffering from relapsing-remitting multiple sclerosis (RRMS).
25. The method of any one of claims 1-23, wherein the human subject is suffering from multiple sclerosis other than RRMS.
26. The method of claim 25, wherein the human subject is suffering from progressive-relapsing multiple sclerosis, secondary progressive multiple sclerosis, or primary progressive multiple sclerosis.
27. The method of any one of claims 1-26, wherein the human subject has previously received administration of a 20 mg/ml dose of glatiramer acetate.
28. The method of any one of claims 1-27, wherein the human subject is a naïve subject or has been previously administered a multiple sclerosis drug other than glatiramer acetate.
29. The method of claim 28, wherein the multiple sclerosis drug other than glatiramer acetate is interferon β -1a, interferon β -1b, mitoxantrone, natalizumab, fingolimod, teriflunomide, or dimethyl fumarate.
30. The method of any one of claims 1-29, wherein the human subject has a genotype comprising:

one or more A alleles at the location of one or more single

nucleotide polymorphisms (SNPs) selected from the group consisting of: kgp10152733, kgp10224254, kgp10305127, kgp10351364, kgp10372946, kgp10404633, kgp10564659, kgp10591989, kgp10594414, kgp10619195, kgp10620244, kgp10633631, kgp10974833, kgp11002881, kgp11285862, kgp11328629, kgp11407560, kgp11514107, kgp11627530, kgp11702474, kgp11711524, kgp11768533, kgp11804835, kgp12083934, kgp12182745, kgp12230354, kgp1224440, kgp124162, kgp12557319, kgp1371881, kgp1699628, kgp1753445, kgp1779254, kgp1786079, kgp18379774, kgp18525257, kgp20163979, kgp2023214, kgp20478926, kgp21171930, kgp2262166, kgp22778566, kgp2465184, kgp24753470, kgp25191871, kgp25216186, kgp25952891, kgp26026546, kgp26533576, kgp27500525, kgp27571222, kgp28532436, kgp28586329, kgp28817122, kgp2958113, kgp29794723, kgp30282494, kgp304921, kgp3205849, kgp3218351, kgp3276689, kgp337461, kgp345301, kgp355027, kgp355723, kgp3593828, kgp3812034, kgp3951463, kgp4162414, kgp4223880, kgp4418535, kgp4543470, kgp4573213, kgp4634875, kgp4755147, kgp4842590, kgp485316, kgp5068397, kgp5334779, kgp5483926, kgp5564995, kgp5869992, kgp5908616, kgp6032617, kgp6038357, kgp6076976, kgp6091119, kgp6127371, kgp61811, kgp6214351, kgp6228750, kgp6236949, kgp6469620, kgp6505544, kgp6507761, kgp6666134, kgp6700691, kgp6772915, kgp6959492, kgp7077322, kgp7117398, kgp7178233, kgp7186699, kgp7506434, kgp759150, kgp7730397, kgp7802182, kgp7804623, kgp7924485, kgp8030775, kgp8036704, kgp8046214, kgp8106690, kgp8110667, kgp8178358, kgp8200264, kgp8372910, kgp841428, kgp8602316, kgp8615910, kgp8793915, kgp8796185, kgp8990121, kgp9018750, kgp9354462, kgp9368119, kgp9410843, kgp9450430, kgp9530088, kgp9627338, kgp9669946, kgp97310, kgp974569, kgp9806386, kgp9884626, rs10049206, rs10124492, rs10125298, rs10162089, rs10203396, rs10251797, rs10278591, rs10489312, rs10492882, rs10498793, rs10501082, rs10510774, rs10512340, rs10815160, rs10816302, rs10841337, rs11029892, rs11029928, rs11192469, rs11559024, rs11648129, rs12013377, rs13394010, rs13415334, rs1478682, rs1544352, rs1545223, rs1604169, rs1621509, rs1644418, rs17029538, rs17400875, rs17449018, rs17577980, rs1858973, rs1894406,

rs1894407, rs197523, rs2058742, rs2071469, rs2071472, rs2139612, rs2241883, rs2309760, rs241440, rs241442, rs241444, rs241445, rs241446, rs241449, rs241453, rs241456, rs2453478, rs2660214, rs2824070, rs2845371, rs2857103, rs2926455, rs343087, rs343092, rs3767955, rs3792135, rs3829539, rs3899755, rs4075692, rs4143493, rs423239, rs4254166, rs4356336, rs4584668, rs4780822, rs4782279, rs5024722, rs6032209, rs6110157, rs623011, rs6497396, rs6845927, rs6895094, rs6899068, rs7024953, rs7028906, rs7029123, rs7062312, rs7187976, rs7191155, rs720176, rs7228827, rs7496451, rs7563131, rs759458, rs7666442, rs7670525, rs7677801, rs7725112, rs7850, rs7862565, rs7948420, rs8035826, rs8053136, rs8055485, rs823829, rs9315047, rs9501224, rs9508832, rs950928, rs9597498, rs9670531, rs9671124, rs9817308, rs9834010, rs9876830 or rs9931211;

one or more C alleles at the location of one or more SNPs selected from the group consisting of: kgp10910719, kgp11077373, kgp11453406, kgp12426624, kgp2045074, kgp22811918, kgp23298674, kgp2709692, kgp28687699, kgp3496814, kgp3669685, kgp3730395, kgp4056892, kgp4370912, kgp5053636, kgp5216209, kgp5292386, kgp6023196, kgp652534, kgp7059449, kgp7189498, kgp7521990, kgp7792268, kgp8303520, kgp9320791, kgp9795732, rs10201643, rs11022778, rs11136970, rs11147439, rs11691553, rs1579771, rs16901784, rs2136408, rs2325911, rs241443, rs2857104, rs3803277, rs3885907, rs4738738, rs4894701, rs502530, rs6032205, rs6687976, rs6718758, rs6835202, rs714342, rs7524868, rs7844274, rs9393727 or rs9671182; or

one or more G alleles at the location of one or more SNPs selected from the group consisting of: kgp10090631, kgp1009249, kgp10412303, kgp10523170, kgp1054273, kgp10558725, kgp10632945, kgp10679353, kgp10788130, kgp10826273, kgp10922969, kgp10948564, kgp10967046, kgp1098237, kgp11010680, kgp11141512, kgp11206453, kgp11210903, kgp1124492, kgp11281589, kgp11356379, kgp11467007, kgp11543962, kgp11580695, kgp11633966, kgp11686146, kgp11843177, kgp12008955, kgp12371757, kgp1285441, kgp13161760, kgp1355977, kgp15390522, kgp1683448, kgp1688752,

kgp1912531, kgp19568724, kgp2092817, kgp2245775, kgp22793211,
kgp22823022, kgp2282938, kgp2299675, kgp2356388, kgp23672937,
kgp23737989, kgp2388352, kgp2391411, kgp24131116, kgp24415534,
kgp2446153, kgp2451249, kgp24729706, kgp25543811, kgp25921291,
kgp26271158, kgp2638591, kgp26528455, kgp2688306, kgp26995430,
kgp270001, kgp2715873, kgp27640141, kgp2788291, kgp2923815,
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rs12494712, rs12943140, rs13002663, rs13419758, rs1380706,
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rs4709792, rs4769060, rs4822644, rs484482, rs543122, rs6535882,
rs6840089, rs7020402, rs7217872, rs7348267, rs7579987,
rs7672014, rs7860748, rs7864679, rs7928078, rs8050872, rs858341,

- rs931570, rs9346979, rs9376361, rs9579566, rs9913349 or rs9931167, or one or more T alleles at the location of kgp18432055, kgp279772, kgp3991733 or kgp7242489.
31. The method of any one of claims 1-30, wherein assaying the level of anti-GA specific antibodies comprises an enzyme-linked immunosorbent assay (ELISA) or a radioimmunoassay.
32. The method of claim 31, wherein assaying the level of anti-GA specific antibodies comprises ELISA.
33. The method of any one of claims 1-32, wherein the baseline level of anti-GA specific antibodies is
- i) the level of anti-GA specific antibodies in a corresponding naïve human subject afflicted with multiple sclerosis;
 - ii) the level of anti-GA specific antibodies in a corresponding naïve healthy human subject;
 - iii) the level of anti-GA specific antibodies in the human subject before the human subject has been administered the after the initial 40 mg/ml dose of glatiramer acetate; or
 - iv) the level of anti-GA specific antibodies in the human subject concurrently with administration of the initial 40 mg/ml dose of glatiramer acetate.
34. The method of any one of claims 1-32, wherein the baseline level of anti-GA specific antibodies is the RA% for
- i) the level of anti-GA specific antibodies in a corresponding naïve human subject afflicted with multiple sclerosis;
 - ii) the level of anti-GA specific antibodies in a corresponding naïve healthy human subject;
 - iii) the level of anti-GA specific antibodies in the human subject before the human subject has been administered the after the initial 40 mg/ml dose of glatiramer acetate; or
 - iv) the level of anti-GA specific antibodies in the human subject concurrently with administration of the initial 40

mg/ml dose of glatiramer acetate.

35. The method of any one of claims 1-34, wherein the ELISA is solid-phase ELISA.
36. A method of inducing anti-glatiramer acetate (GA) specific antibodies in a human subject afflicted with multiple sclerosis, comprising administration to the human subject of three subcutaneous injections of a 40 mg/ml dose of glatiramer acetate per week for at least 12 months, such that the level of anti-GA specific antibodies in the blood or serum of the human subject
- i) increases for up to 6 months after an initial 40 mg/ml dose of glatiramer acetate of the administration is administered to the human subject;
 - ii) increases at a greater rate during the first month after the initial 40 mg/ml dose of glatiramer acetate compared to the rate of increase after the first month to the third month after the initial 40 mg/ml dose of glatiramer acetate;
 - iii) peaks at 3 or 6 months or between 3 and 6 months after the initial 40 mg/ml dose of glatiramer acetate; and
 - iv) is higher than baseline at least 12 months after the initial 40 mg/ml dose of glatiramer acetate,

wherein the 40 mg/ml dose of glatiramer acetate is in a prefilled syringe containing 1ml of an aqueous pharmaceutical solution of 40mg/ml of glatiramer acetate and 40mg/ml mannitol, and wherein the aqueous pharmaceutical solution

- 5 a) has a viscosity in the range of 2.0-3.5 cPa; or
- b) has an osmolality in the range of 270-330 mosmol/Kg.

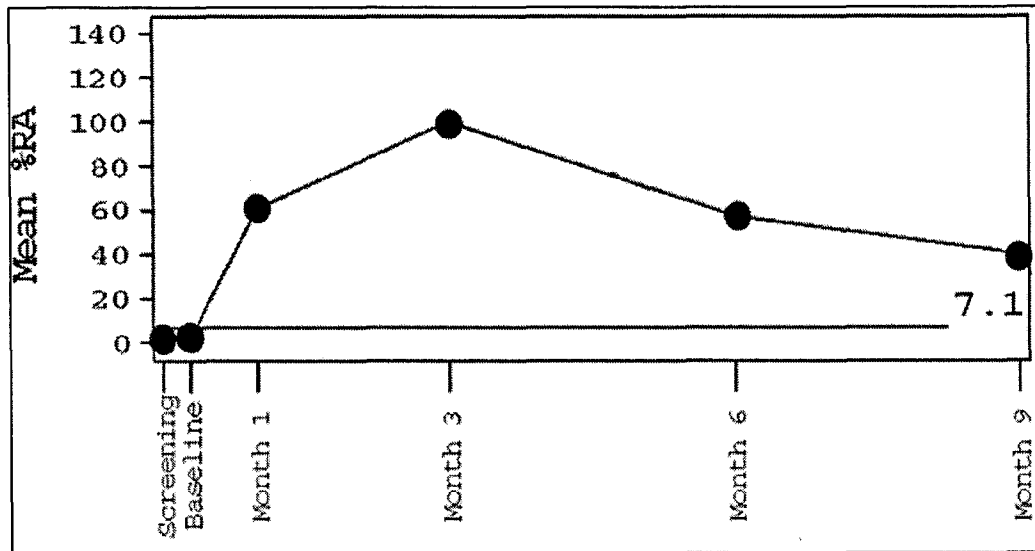


Figure 1

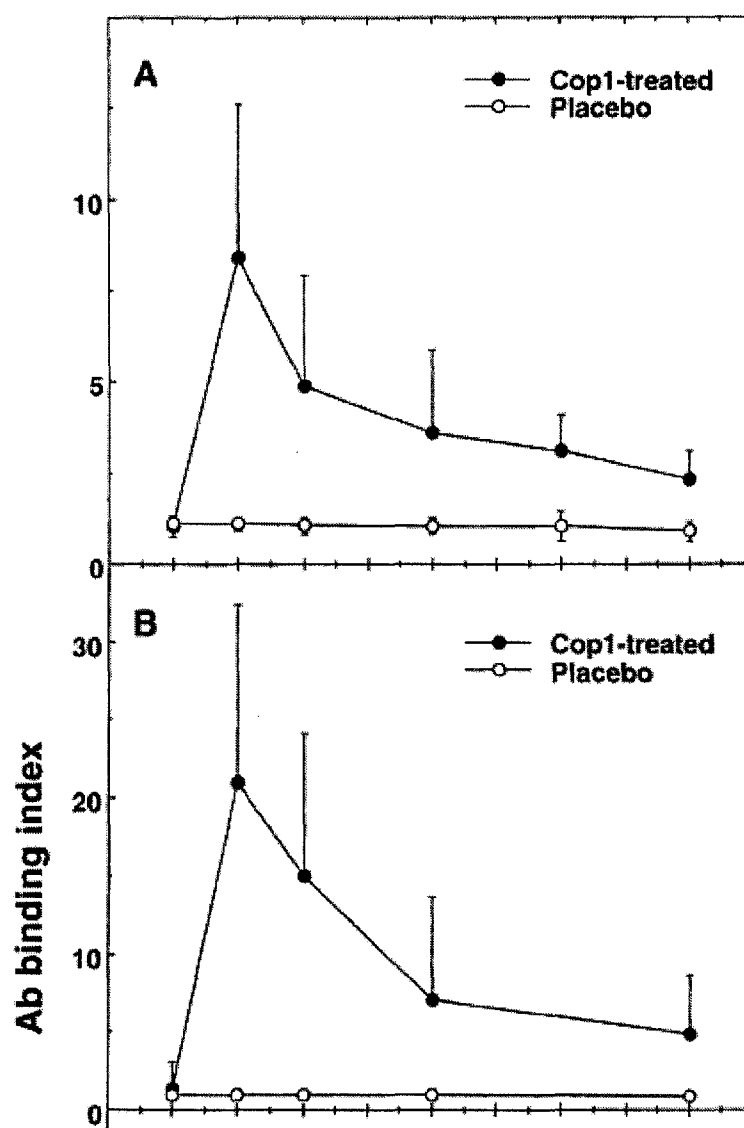


FIGURE 2

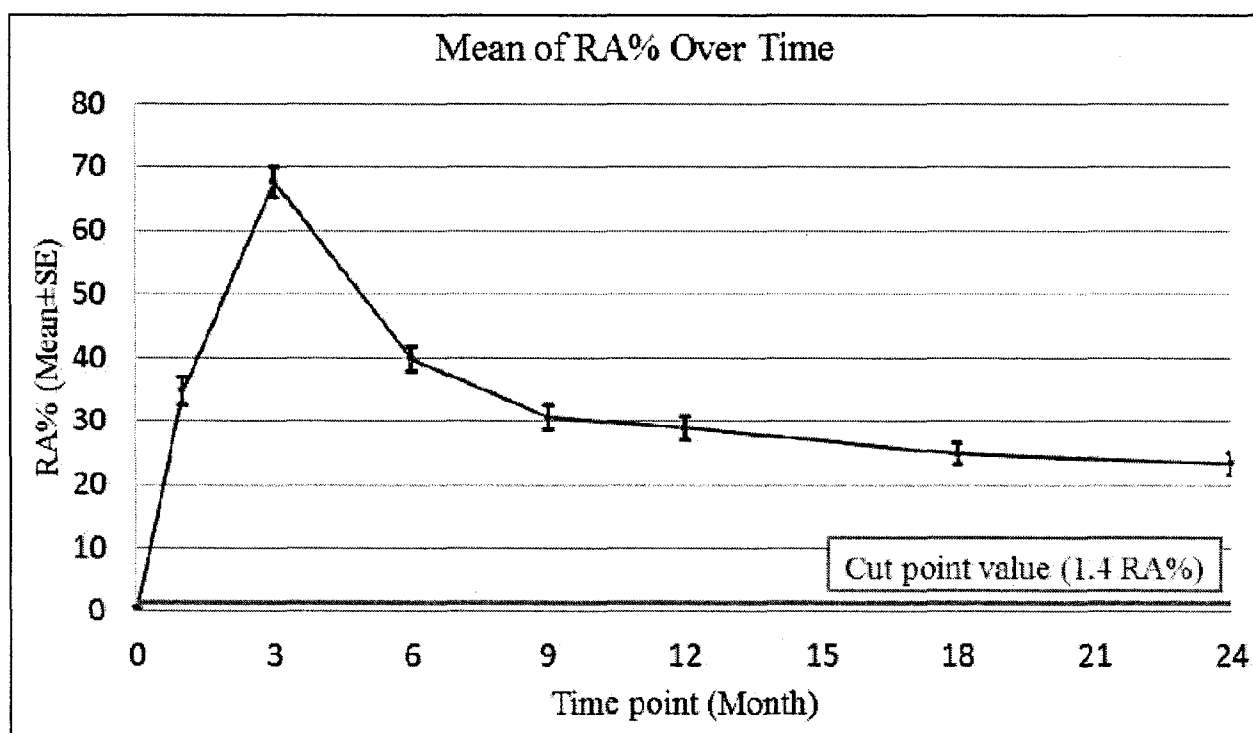


Figure 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2016/015369

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61K 38/17 (2016.01) CPC - A61K 38/17 (2016.02) According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61K 31/00, 38/00, 38/16, 38/17 (2016.01) CPC - A61K 31/00, 38/00, 38/16, 38/17 (2016.02) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched U.S. Classes - 514/1, 1.1, 17.7, 17.9 (keyword delimited) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Orbit, Google Patents, PubMed, Google. Search terms used: induce anti-glatiramer acetate specific antibodies response profile multiple sclerosis subcutaneous injections		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2012/0121619 A1 (KASPER et al) 17 May 2012 (17.05.2012) entire document	1-4, 7-10, 36
A	BOMPREZZI et al. "Glatiramer Acetate-Specific Antibody Titres in Patients with Relapsing/Remitting Multiple Sclerosis and in Experimental Autoimmune Encephalomyelitis," Scandinavian Journal of Immunology, 7 August 2011 (07.08.2011), Vol. 74, Iss. 3, Pgs. 219-226. entire document	1-4, 7-10, 36
A	TSELIS et al. "Glatiramer acetate in the treatment of multiple sclerosis," Neuropsychiatric Disease and Treatment, 15 May 2007 (15.05.2007), Vol. 3, Iss. 2, Pgs. 259-267. entire document	1-4, 7-10, 36
A	US 8,394,763 B2 (FORTE et al) 12 March 2013 (12.03.2013) entire document	1-4, 7-10, 36
A	US 7,754,216 B2 (SCARISBRICK et al) 13 July 2010 (13.07.2010) entire document	1-4, 7-10, 36
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 01 April 2016		Date of mailing of the international search report 22 APR 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300		Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2016/015369

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 5, 6, 11-35
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.