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(54) Title: COMPOSITIONS, DEVICES, AND METHODS OF FUNCTIONAL DYSPEPSIA SENSITIVITY TESTING

(57) Abstract: Contemplated test kits and methods for food sensitivity are based on rational-based selection of food preparations with established discriminatory p-value. Particularly preferred kits include those with a minimum number of food preparations that have an average discriminatory p-value of ≤ 0.07 as determined by their raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value. In further contemplated aspects, compositions and methods for food sensitivity are also stratified by gender to further enhance predictive value.

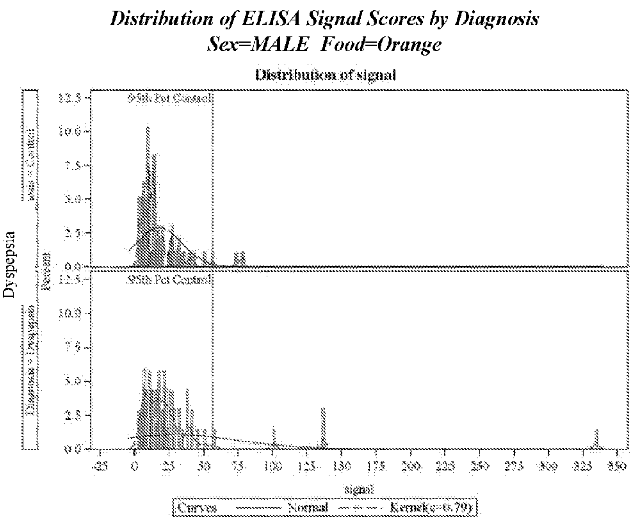

Figure 1A

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COMPOSITIONS, DEVICES, AND METHODS OF FUNCTIONAL DYSPEPSIA SENSITIVITY TESTING

Related Applications

[0001] This application claims priority to our U.S. provisional patent application with the serial number 62/305680 filed March 9, 2016, which is incorporated by reference herein in its entirety.

Field of the Invention

[0002] The field of the invention is sensitivity testing for food intolerance, and especially as it relates to testing and possible elimination of selected food items as trigger foods for patients diagnosed with or suspected to have Functional Dyspepsia.

Background

[0003] The background description includes information that may be useful in understanding the present invention. It is not an admission that any of the information provided herein is prior art or relevant to the presently claimed invention, or that any publication specifically or implicitly referenced is prior art.

[0004] Food sensitivity, especially as it relates to Functional Dyspepsia (a type of chronic, systemic disorder), often presents with the upset stomach, the pain and discomfort in the upper belly near ribs, vomiting, and/or difficulty in swallowing, and underlying causes of Functional Dyspepsia are not well understood in the medical community. Most typically, Functional Dyspepsia is diagnosed by questionnaires by medical practitioners regarding symptoms, and sometimes by upper endoscopy or blood test. Unfortunately, treatment of Functional Dyspepsia is often less than effective and may present new difficulties due to immune suppressive or modulatory effects. Elimination of other one or more food items has also shown promise in at least reducing incidence and/or severity of the symptoms. However, Functional Dyspepsia is often quite diverse with respect to dietary items triggering symptoms, and no standardized test to help identify trigger food items with a reasonable degree of certainty is known, leaving such patients often to trial-and-error.

[0005] While there are some commercially available tests and labs to help identify trigger foods, the quality of the test results from these labs is generally poor as is reported by a consumer advocacy group (*e.g.,* http://www.which.co.uk/news/2008/08/food-allergy-tests-could-risk-your-health-154711/). Most notably, problems associated with these tests and labs were high false positive rates, high false negative rates, high intra-patient variability, and inter-laboratory variability, rendering such tests nearly useless. Similarly, further inconclusive and highly variable test results were also reported elsewhere (Alternative Medicine Review, Vol. 9, No. 2, 2004: pp 198-207), and the authors concluded that this may be due to food reactions and food sensitivities occurring via a number of different mechanisms. For example, not all Functional Dyspepsia patients show positive response to food A, and not all Functional Dyspepsia patients show negative response to food B. Thus, even if a Functional Dyspepsia patient shows positive response to food A, removal of food A from the patient's diet may not relieve the patient's Functional Dyspepsia symptoms. In other words, it is not well determined whether food samples used in the currently available tests are properly selected based on the high probabilities to correlate sensitivities to those food samples to Functional Dyspepsia.

[0006] All publications identified herein are incorporated by reference to the same extent as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference. Where a definition or use of a term in an incorporated reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies and the definition of that term in the reference does not apply.

[0007] Thus, even though various tests for food sensitivities are known in the art, all or almost all of them suffer from one or more disadvantages. Therefore, there is still a need for improved compositions, devices, and methods of food sensitivity testing, especially for identification and possible elimination of trigger foods for patients identified with or suspected of having Functional Dyspepsia.

Summary

[0008] The subject matter described herein provides systems and methods for testing food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia. One aspect of the disclosure is a test kit with for testing food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia. The test kit includes a plurality of distinct food preparations coupled to individually addressable respective solid carriers. The plurality of distinct food preparations have an average discriminatory p-value of ≤ 0.07 as determined by

raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value. In some embodiments, the average discriminatory p-value is determined by a process, which includes comparing assay values of a first patient test cohort that is diagnosed with or suspected of having Functional Dyspepsia with assay values of a second patient test cohort that is not diagnosed with or suspected of having Functional Dyspepsia

[0009] Another aspect of the embodiments described herein includes a method of testing food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia. The method includes a step of contacting a food preparation with a bodily fluid of a patient that is diagnosed with or suspected to have Functional Dyspepsia. The bodily fluid is associated with gender identification. In certain embodiments, the step of contacting is performed under conditions that allow IgG from the bodily fluid to bind to at least one component of the food preparation. The method continues with a step of measuring IgG bound to the at least one component of the food preparation to obtain a signal, and then comparing the signal to a gender-stratified reference value for the food preparation using the gender identification to obtain a result. Then, the method also includes a step of updating or generating a report using the result.

[0010] Another aspect of the embodiments described herein includes a method of generating a test for food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia. The method includes a step of obtaining test results for a plurality of distinct food preparations. The test results are based on bodily fluids of patients diagnosed with or suspected to have Functional Dyspepsia and bodily fluids of a control group not diagnosed with or not suspected to have Functional Dyspepsia. The method also includes a step of stratifying the test results by gender for each of the distinct food preparations. Then the method continues with a step of assigning for a predetermined percentile rank a different cutoff value for male and female patients for each of the distinct food preparations.

[0011] Still another aspect of the embodiments described herein includes a use of a plurality of distinct food preparations coupled to individually addressable respective solid carriers in a diagnosis of Functional Dyspepsia. The plurality of distinct food preparations are selected based on their average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

[0012] Various objects, features, aspects and advantages of the embodiments described herein will become more apparent from the following detailed description of preferred embodiments, along with the accompanying drawing figures in which like numerals represent like components.

Brief Description of The Drawings

[0013] **Table 1** shows a list of food items from which food preparations can be prepared.

[0014] **Table 2** shows statistical data of foods ranked according to 2-tailed FDR multiplicity-adjusted p-values.

[0015] **Table 3** shows statistical data of ELISA score by food and gender.

[0016] **Table 4** shows cutoff values of foods for a predetermined percentile rank.

[0017] **Figure 1A** illustrates ELISA signal score of male Functional Dyspepsia patients and control tested with orange.

[0018] **Figure 1B** illustrates a distribution of percentage of male Functional Dyspepsia subjects exceeding the 90^{th} and 95^{th} percentile tested with orange.

[0019] **Figure 1C** illustrates a signal distribution in women along with the 95^{th} percentile cutoff as determined from the female control population tested with orange.

[0020] **Figure 1D** illustrates a distribution of percentage of female Functional Dyspepsia subjects exceeding the 90^{th} and 95^{th} percentile tested with orange.

[0021] **Figure 2A** illustrates ELISA signal score of male Functional Dyspepsia patients and control tested with barley.

[0022] **Figure 2B** illustrates a distribution of percentage of male Functional Dyspepsia subjects exceeding the 90^{th} and 95^{th} percentile tested with barley.

[0023] **Figure 2C** illustrates a signal distribution in women along with the 95^{th} percentile cutoff as determined from the female control population tested with barley.

[0024] **Figure 2D** illustrates a distribution of percentage of female Functional Dyspepsia subjects exceeding the 90^{th} and 95^{th} percentile tested with barley.

[0025] Figure 3A illustrates ELISA signal score of male Functional Dyspepsia patients and control tested with oat.

[0026] Figure 3B illustrates a distribution of percentage of male Functional Dyspepsia subjects exceeding the 90th and 95th percentile tested with oat.

[0027] Figure 3C illustrates a signal distribution in women along with the 95th percentile cutoff as determined from the female control population tested with oat.

[0028] Figure 3D illustrates a distribution of percentage of female Functional Dyspepsia subjects exceeding the 90th and 95th percentile tested with oat.

[0029] Figure 4A illustrates ELISA signal score of male Functional Dyspepsia patients and control tested with malt.

[0030] Figure 4B illustrates a distribution of percentage of male Functional Dyspepsia subjects exceeding the 90th and 95th percentile tested with malt.

[0031] Figure 4C illustrates a signal distribution in women along with the 95th percentile cutoff as determined from the female control population tested with malt.

[0032] Figure 4D illustrates a distribution of percentage of female Functional Dyspepsia subjects exceeding the 90th and 95th percentile tested with malt.

[0033] Figure 5A illustrates distributions of Functional Dyspepsia subjects by number of foods that were identified as trigger foods at the 90th percentile.

[0034] Figure 5B illustrates distributions of Functional Dyspepsia subjects by number of foods that were identified as trigger foods at the 95th percentile.

[0035] Table 5A shows raw data of Functional Dyspepsia patients and control with number of positive results based on the 90th percentile.

[0036] Table 5B shows raw data of Functional Dyspepsia patients and control with number of positive results based on the 95th percentile.

[0037] Table 6A shows statistical data summarizing the raw data of Functional Dyspepsia patient populations shown in Table 5A.

[0038] Table 6B shows statistical data summarizing the raw data of Functional Dyspepsia patient populations shown in Table 5B.

[0039] Table 7A shows statistical data summarizing the raw data of control populations shown in Table 5A.

[0040] Table 7B shows statistical data summarizing the raw data of control populations shown in Table 5B.

[0041] Table 8A shows statistical data summarizing the raw data of Functional Dyspepsia patient populations shown in Table 5A transformed by logarithmic transformation.

[0042] Table 8B shows statistical data summarizing the raw data of Functional Dyspepsia patient populations shown in Table 5B transformed by logarithmic transformation.

[0043] Table 9A shows statistical data summarizing the raw data of control populations shown in Table 5A transformed by logarithmic transformation.

[0044] Table 9B shows statistical data summarizing the raw data of control populations shown in Table 5B transformed by logarithmic transformation.

[0045] Table 10A shows statistical data of an independent T-test to compare the geometric mean number of positive foods between the Functional Dyspepsia and non-Functional Dyspepsia samples based on the 90^{th} percentile.

[0046] Table 10B shows statistical data of an independent T-test to compare the geometric mean number of positive foods between the Functional Dyspepsia and non-Functional Dyspepsia samples based on the 95^{th} percentile.

[0047] Table 11A shows statistical data of a Mann-Whitney test to compare the geometric mean number of positive foods between the Functional Dyspepsia and non-Functional Dyspepsia samples based on the 90^{th} percentile.

[0048] Table 11B shows statistical data of a Mann-Whitney test to compare the geometric mean number of positive foods between the Functional Dyspepsia and non-Functional Dyspepsia samples based on the 95^{th} percentile.

[0049] Figure 6A illustrates a box and whisker plot of data shown in Table 5A.

[0050] Figure 6B illustrates a notched box and whisker plot of data shown in Table 5A.

[0051] Figure 6C illustrates a box and whisker plot of data shown in Table 5B.

[0052] Figure 6D illustrates a notched box and whisker plot of data shown in Table 5B.

[0053] Table 12A shows statistical data of a Receiver Operating Characteristic (ROC) curve analysis of data shown in Tables 5A-11A.

[0054] Table 12B shows statistical data of a Receiver Operating Characteristic (ROC) curve analysis of data shown in Tables 5B-11B.

[0055] Figure 7A illustrates the ROC curve corresponding to the statistical data shown in Table 12A.

[0056] Figure 7B illustrates the ROC curve corresponding to the statistical data shown in Table 12B.

[0057] Table 13A shows a statistical data of performance metrics in predicting Functional Dyspepsia status among female patients from number of positive foods based on the 90^{th} percentile.

[0058] Table 13B shows a statistical data of performance metrics in predicting Functional Dyspepsia status among male patients from number of positive foods based on the 90^{th} percentile.

[0059] Table 14A shows a statistical data of performance metrics in predicting Functional Dyspepsia status among female patients from number of positive foods based on the 95^{th} percentile.

[0060] Table 14B shows a statistical data of performance metrics in predicting Functional Dyspepsia status among male patients from number of positive foods based on the 95^{th} percentile

Detailed Description

[0061] The inventors have discovered that food preparations used in food tests to identify trigger foods in patients diagnosed with or suspected to have Functional Dyspepsia are not equally well predictive and/or associated with Functional Dyspepsia/Functional Dyspepsia symptoms. Indeed, various experiments have revealed that among a wide variety of food items certain food items are highly predictive/associated with Functional Dyspepsia whereas others have no statistically significant association with Functional Dyspepsia.

[0062] Even more unexpectedly, the inventors discovered that in addition to the high variability of food items, gender variability with respect to response in a test plays a substantial role in the determination of association or a food item with Functional Dyspepsia. Consequently, based on the inventors' findings and further contemplations, test kits and methods are now presented with substantially higher predictive power in the choice of food items that could be eliminated for reduction of Functional Dyspepsia signs and symptoms.

[0063] The following discussion provides many example embodiments of the inventive subject matter. Although each embodiment represents a single combination of inventive elements, the inventive subject matter is considered to include all possible combinations of the disclosed elements. Thus if one embodiment comprises elements A, B, and C, and a second embodiment comprises elements B and D, then the inventive subject matter is also considered to include other remaining combinations of A, B, C, or D, even if not explicitly disclosed.

[0064] In some embodiments, the numbers expressing quantities or ranges, used to describe and claim certain embodiments of the invention are to be understood as being modified in some instances by the term "about." Accordingly, in some embodiments, the numerical parameters set forth in the written description and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable. The numerical values presented in some embodiments of the invention may contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements. Unless the context dictates the contrary, all ranges set forth herein should be interpreted as being inclusive of their endpoints and open-ended ranges should be interpreted to include only commercially practical values. Similarly, all lists of values should be considered as inclusive of intermediate values unless the context indicates the contrary.

[0065] As used in the description herein and throughout the claims that follow, the meaning of "a," "an," and "the" includes plural reference unless the context clearly dictates otherwise. Also, as used in the description herein, the meaning of "in" includes "in" and "on" unless the context clearly dictates otherwise.

[0066] All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (*e.g.,* "such as") provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0067] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member can be referred to and claimed individually or in any combination with other members of the group or other elements found herein. One or more members of a group can be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is herein deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0068] In one aspect, the inventors therefore contemplate a test kit or test panel that is suitable for testing food intolerance in patients where the patient is diagnosed with or suspected to have Functional Dyspepsia. Most preferably, such test kit or panel will include a plurality of distinct food preparations (*e.g.,* raw or processed extract, preferably aqueous extract with optional co-solvent, which may or may not be filtered) that are coupled to individually addressable respective solid carriers (*e.g.,* in a form of an array or a micro well plate), wherein the distinct food preparations have an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

[0069] In some embodiments, the numbers expressing quantities of ingredients, properties such as concentration, reaction conditions, and so forth, used to describe and claim certain embodiments of the invention are to be understood as being modified in some instances by the term "about." Accordingly, in some embodiments, the numerical parameters set forth in the written description and attached claims are approximations that can vary depending upon the desired properties sought to be obtained by a particular embodiment. In some embodiments, the numerical parameters should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of some embodiments of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as practicable. The numerical values presented in some embodiments of the invention may contain certain errors necessarily resulting from the standard deviation found in their respective testing measurements. Moreover, and unless the context dictates the contrary, all ranges set forth herein should be interpreted as being inclusive of their endpoints and open-ended ranges should be interpreted to include only commercially practical values. Similarly, all lists of values should be considered as inclusive of intermediate values unless the context indicates the contrary.

[0070] While not limiting to the inventive subject matter, food preparations will typically be drawn from foods generally known or suspected to trigger signs or symptoms of Functional Dyspepsia. Particularly suitable food preparations may be identified by the experimental procedures outlined below. Thus, it should be appreciated that the food items need not be limited to the items described herein, but that all items are contemplated that can be identified by the methods presented herein. Therefore, exemplary food preparations include at least two, at least four, at least eight, or at least 12 food preparations prepared from foods 1-37 of Table 2. Still further especially contemplated food items and food additives from which food preparations can be prepared are listed in **Table 1**.

[0071] Using bodily fluids from patients diagnosed with or suspected to have Functional Dyspepsia and healthy control group individuals (*i.e.*, those not diagnosed with or not suspected to have Functional Dyspepsia), numerous additional food items may be identified. Preferably, such identified food items will have high discriminatory power and as such have a p-value of ≤ 0.15, more preferably ≤ 0.10, and most preferably ≤ 0.05 as determined by raw p-value, and/or a p-value of ≤ 0.10, more preferably ≤ 0.08, and most preferably ≤ 0.07 as determined by False Discovery Rate (FDR) multiplicity adjusted p-value.

[0072] In certain embodiments, such identified food preparations will have high discriminatory power and, as such, will have a p-value of ≤ 0.15, ≤ 0.10, or even ≤ 0.05 as determined by raw p-value, and/or a p-value of ≤ 0.10, ≤ 0.08, or even ≤ 0.07 as determined by False Discovery Rate (FDR) multiplicity adjusted p-value.

[0073] Therefore, where a panel has multiple food preparations, it is contemplated that the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value, or even more preferably an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value. In further preferred aspects, it should be appreciated that the FDR multiplicity adjusted p-value may be adjusted for at least one of age and gender, and most preferably adjusted for both age and gender. On the other hand, where a test kit or panel is stratified for use with a single gender, it is also contemplated that in a test kit or panel at least 50% (and more typically 70% or all) of the plurality of distinct food preparations, when adjusted for a single gender, have an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value. Furthermore, it should be appreciated that other stratifications (*e.g.,* dietary preference, ethnicity, place of residence, genetic predisposition or family history, etc.) are also contemplated, and the person of ordinary skill in the art (PHOSITA) will be readily appraised of the appropriate choice of stratification.

[0074] The recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (*e.g.,* "such as") provided with respect to certain embodiments herein is intended merely to better illuminate the invention and does not pose a limitation on the scope of the invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the invention.

[0075] Of course, it should be noted that the particular format of the test kit or panel may vary considerably and contemplated formats include micro well plates, dip sticks, membrane-bound arrays, etc. Consequently, the solid carrier to which the food preparations are coupled may include wells of a multiwell plate, a (*e.g.,* color-coded or magnetic) bead, or an adsorptive film (*e.g.,* nitrocellulose or micro/nanoporous polymeric film), or an electrical sensor, (*e.g.,* a printed copper sensor or microchip).

[0076] Consequently, the inventors also contemplate a method of testing food intolerance in patients that are diagnosed with or suspected to have Functional Dyspepsia. Most typically, such methods will include a step of contacting a food preparation with a bodily fluid (*e.g.,* whole blood, plasma, serum, saliva, or a fecal suspension) of a patient that is diagnosed with or suspected to have Functional Dyspepsia, and wherein the bodily fluid is associated with a gender identification. As noted before, the step of contacting is preferably performed under conditions that allow IgG (or IgE or IgA or IgM) from the bodily fluid to bind to at least one component of the food preparation, and the IgG bound to the component(s) of the food preparation are then quantified/measured to obtain a signal. In some embodiments, the signal is then compared against a gender-stratified reference value (*e.g.,* at least a 90th percentile value) for the food preparation using the gender identification to obtain a result, which is then used to update or generate a report (*e.g.,* written medical report; oral report of results from doctor to patient; written or oral directive from physician based on results).

[0077] In certain embodiments, such methods will not be limited to a single food preparation, but will employ multiple different food preparations. As noted before, suitable food preparations can be identified using various methods as described below, however, especially preferred food preparations include foods 1-37 of Table 2, and/or items of Table 1. As also noted above, it is generally preferred that at least some, or all of the different food preparations have an average discriminatory p-value of ≤ 0.07 (or ≤ 0.05, or ≤ 0.025) as determined by raw p-value, and/or or an average discriminatory p-value of ≤ 0.10 (or ≤ 0.08, or ≤ 0.07) as determined by FDR multiplicity adjusted p-value.

[0078] While in certain embodiments food preparations are prepared from single food items as crude extracts, or crude filtered extracts, it is contemplated that food preparations can be prepared from mixtures of a plurality of food items (*e.g.,* a mixture of citrus comprising lemon, orange, and a grapefruit, a mixture of yeast comprising baker's yeast and brewer's yeast, a mixture of rice comprising a brown rice and white rice, a mixture of sugars comprising honey, malt, and cane sugar. In some embodiments, it is also contemplated that food preparations can be prepared from purified food antigens or recombinant food antigens.

[0079] As it is generally preferred that the food preparation is immobilized on a solid surface (typically in an addressable manner), it is contemplated that the step of measuring the IgG or other type of antibody bound to the component of the food preparation is performed via an ELISA test. Exemplary solid surfaces include, but are not limited to, wells in a multiwell plate, such that each food preparation may be isolated to a separate microwell. In certain embodiments, the food preparation will be coupled to, or immobilized on, the solid surface. In other embodiments, the food preparation(s) will be coupled to a molecular tag that allows for binding to human immunoglobulins (*e.g.,* IgG) in solution.

[0080] Viewed from a different perspective, the inventors also contemplate a method of generating a test for food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia. Because the test is applied to patients already diagnosed with or suspected to have Functional Dyspepsia, the authors do not contemplate that the method has a diagnostic purpose. Instead, the method is for identifying triggering food items among already diagnosed or suspected Functional Dyspepsia patients. Such test will typically include a step of obtaining one or more test results (*e.g.,* ELISA) for various distinct food preparations, wherein the test results are based on bodily fluids (*e.g.,* blood saliva, fecal suspension) of patients diagnosed with or suspected to have Functional Dyspepsia and bodily fluids of a control group not diagnosed with or not suspected to have Functional Dyspepsia. Most preferably, the test results are then stratified by gender for each of the distinct food preparations, a different cutoff value for male and female patients for each of the distinct food preparations (*e.g.,* cutoff value for male and female patients has a difference of at least 10% (abs)) is assigned for a predetermined percentile rank (*e.g.,* 90th or 95th percentile).

[0081] As noted earlier, and while not limiting to the inventive subject matter, it is contemplated that the distinct food preparations include at least two (or six, or ten, or 15) food preparations prepared from food items selected from the group consisting of foods 1-37 of Table 2, and/or items of Table 1. On the other hand, where new food items are tested, it should be appreciated that the distinct food preparations include a food preparation prepared from a food items other than foods 1-37 of Table 2. Regardless of the particular choice of food items, it is generally preferred however, that the distinct food preparations have an average discriminatory p-value of ≤ 0.07 (or ≤ 0.05, or ≤ 0.025) as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 (or ≤ 0.08, or ≤ 0.07) as determined by FDR multiplicity adjusted p-value. Exemplary aspects and protocols, and considerations are provided in the experimental description below.

[0082] Thus, it should be appreciated that by having a high-confidence test system as described herein, the rate of false-positive and false negatives can be significantly reduced, and especially where the test systems and methods are gender stratified or adjusted for gender differences as shown below. Such advantages have heretofore not been realized and it is expected that the systems and methods presented herein will substantially increase the predictive power of food sensitivity tests for patients diagnosed with or suspected to have Functional Dyspepsia.

Experiments

[0083] General Protocol for food preparation generation: Commercially available food extracts (available from Biomerica Inc., 17571 Von Karman Ave, Irvine, CA 92614) prepared from the edible portion of the respective raw foods were used to prepare ELISA plates following the manufacturer's instructions.

[0084] For some food extracts, the inventors expect that food extracts prepared with specific procedures to generate food extracts provides more superior results in detecting elevated IgG reactivity in Functional Dyspepsia patients compared to commercially available food extracts. For example, for grains and nuts, a three-step procedure of generating food extracts is preferred. The first step is a defatting step. In this step, lipids from grains and nuts are extracted by contacting the flour of grains and nuts with a non-polar solvent and collecting residue. Then, the defatted grain or nut flour are extracted by contacting the flour with elevated pH to obtain a mixture and removing the solid from the mixture to obtain the liquid extract. Once the liquid extract is generated, the liquid extract is stabilized by adding an aqueous formulation. In a preferred embodiment, the aqueous formulation includes a sugar alcohol, a metal chelating agent, protease inhibitor, mineral salt, and buffer component 20-50 mM of buffer from 4-9 pH. This formulation allowed for long term storage at -70 ºC and multiple freeze-thaws without a loss of activity.

[0085] For another example, for meats and fish, a two step procedure of generating food extract is preferred. The first step is an extraction step. In this step, extracts from raw, uncooked meats or fish are generated by emulsifying the raw, uncooked meats or fish in an aqueous buffer formulation in a high impact pressure processor. Then, solid materials are removed to obtain liquid extract. Once the liquid extract is generated, the liquid extract is stabilized by adding an aqueous formulation. In a preferred embodiment, the aqueous formulation includes a sugar alcohol, a metal chelating agent, protease inhibitor, mineral salt, and buffer component 20-50 mM of buffer from 4-9 pH. This formulation allowed for long term storage at -70 °C and multiple freeze-thaws without a loss of activity.

[0086] For still another example, for fruits and vegetables, a two step procedure of generating food extract is preferred. The first step is an extraction step. In this step, liquid extracts from fruits or vegetables are generated using an extractor (*e.g.,* masticating juicer, etc) to pulverize foods and extract juice. Then, solid materials are removed to obtain liquid extract. Once the liquid extract is generated, the liquid extract is stabilized by adding an aqueous formulation. In a preferred embodiment, the aqueous formulation includes a sugar alcohol, a metal chelating agent, protease inhibitor, mineral salt, and buffer component 20-50 mM of buffer from 4-9 pH. This formulation allowed for long term storage at -70 °C and multiple freeze-thaws without a loss of activity.

[0087] <u>Blocking of ELISA plates</u>: To optimize signal to noise, plates will be blocked with a proprietary blocking buffer. In a preferred embodiment, the blocking buffer includes 20-50 mM of buffer from 4-9 pH, a protein of animal origin and a short chain alcohol. Other blocking buffers, including several commercial preparations, can be attempted but may not provide adequate signal to noise and low assay variability required.

[0088] <u>ELISA preparation and sample testing</u>: Food antigen preparations were immobilized onto respective microtiter wells following the manufacturer's instructions. For the assays, the food antigens were allowed to react with antibodies present in the patients' serum, and excess serum proteins were removed by a wash step. For detection of IgG antibody binding, enzyme labeled anti-IgG antibody conjugate was allowed to react with antigen-antibody complex. A color was developed by the addition of a substrate that reacts with the coupled enzyme. The color intensity was measured and is directly proportional to the concentration of IgG antibody specific to a particular food antigen.

[0089] <u>Methodology to determine ranked food list in order of ability of ELISA signals to distinguish Functional Dyspepsia from control subjects:</u> Out of an initial selection (*e.g.,* 100 food items, or 150 food items, or even more), samples can be eliminated prior to analysis due to low consumption in an intended population. In addition, specific food items can be used as being representative of the a larger more generic food group, especially where prior testing has established a correlation among different species within a generic group (most preferably in both genders, but also suitable for correlation for a single gender). For example, Thailand Shrimp could be dropped in favor of U.S. Gulf White Shrimp as representative of the "shrimp" food group, or King Crab could be dropped in favor of Dungeness Crab as representative of the "crab" food group In further preferred aspects, the final list foods will be shorter than 50 food items, and more preferably equal or less than of 40 food items.

[0090] Since the foods ultimately selected for the food intolerance panel will not be specific for a particular gender, a gender-neutral food list is necessary. Since the observed sample will be at least initially imbalanced by gender (*e.g.*, Controls: 40% female, Functional Dyspepsia: 51% female), differences in ELISA signal magnitude strictly due to gender will be removed by modeling signal scores against gender using a two-sample t-test and storing the residuals for further analysis. For each of the tested foods, residual signal scores will be compared between Functional Dyspepsia and controls using a permutation test on a two-sample t-test with a relative high number of resamplings (*e.g.*, >1,000, more preferably >10,000, even more preferably >50,000). The Satterthwaite approximation can then be used for the denominator degrees of freedom to account for lack of homogeneity of variances, and the 2-tailed permuted p-value will represent the raw p-value for each food. False Discovery Rates (FDR) among the comparisons, will be adjusted by any acceptable statistical procedures (*e.g.*, Benjamini-Hochberg, Family-wise Error Rate (FWER), Per Comparison Error Rate (PCER), etc.).

[0091] Foods were then ranked according to their 2-tailed FDR multiplicity-adjusted p-values. Foods with adjusted p-values equal to or lower than the desired FDR threshold are deemed to have significantly higher signal scores among Functional Dyspepsia than control subjects and therefore deemed candidates for inclusion into a food intolerance panel. A typical result that is representative of the outcome of the statistical procedure is provided in **Table 2**. Here the ranking of foods is according to 2-tailed permutation T-test p-values with FDR adjustment.

[0092] Based on earlier experiments (data not shown here, see US 62/079783), the inventors contemplate that even for the same food preparation tested, the ELISA score for at least several food items will vary dramatically, and exemplary raw data are provided in **Table 3**. As should be readily appreciated, data unstratified by gender will therefore lose significant explanatory power where the same cutoff value is applied to raw data for male and female data. To overcome such disadvantage, the inventors therefore contemplate stratification of the data by gender as described below.

[0093] Statistical Method for Cutpoint Selection for each Food: The determination of what ELISA signal scores would constitute a “positive” response can be made by summarizing the distribution of signal scores among the Control subjects. For each food, Functional Dyspepsia subjects who have observed scores greater than or equal to selected quantiles of the Control subject distribution will be deemed “positive”. To attenuate the influence of any one subject on cutpoint determination, each food-specific and gender-specific dataset will be bootstrap resampled 1000 times. Within each bootstrap replicate, the 90th and 95th percentiles of the Control signal scores will be determined. Each Functional Dyspepsia subject in the bootstrap sample will be compared to the 90th and 95% percentiles to determine whether he/she had a “positive” response. The final 90th and 95th percentile-based cutpoints for each food and gender will be computed as the average 90th and 95th percentiles across the 1000 samples. The number of foods for which each Functional Dyspepsia subject will be rated as “positive” was computed by pooling data across foods. Using such method, the inventors will be now able to identify cutoff values for a predetermined percentile rank that in most cases was substantially different as can be taken from **Table 4**.

[0094] Typical examples for the gender difference in IgG response in blood with respect to orange is shown in **Figures 1A-1D,** where **Figure 1A** shows the signal distribution in men along with the 95th percentile cutoff as determined from the male control population. **Figure 1B** shows the distribution of percentage of male Functional Dyspepsia subjects exceeding the 90th and 95th percentile, while **Figure 1C** shows the signal distribution in women along with the 95th percentile cutoff as determined from the female control population. **Figure 1D** shows the distribution of percentage of female Functional Dyspepsia subjects exceeding the 90th and 95th percentile. In the same fashion, **Figures 2A-2D** exemplarily depict the differential response to barley, **Figures 3A-3D** exemplarily depict the differential response to oat, and **Figures 4A-4D** exemplarily depict the differential response to malt. **Figures 5A-5B** show the distribution of Functional Dyspepsia subjects by number of foods that were identified as trigger foods at the 90th percentile (5A) and 95th percentile (5B). Inventors contemplate that regardless of the particular food items, male and female responses will be notably distinct.

[0095] It should be noted that nothing in the art have provided any predictable food groups related to Functional Dyspepsia that is gender-stratified. Thus, a discovery of food items that show distinct responses by gender is a surprising result, which could not be obviously expected in view of all previously available arts. In other words, selection of food items based on gender stratification provides an unexpected technical effect such that statistical significances for particular food items as triggering food among male or female Functional Dyspepsia patients have been significantly improved.

[0096] Normalization of IgG Response Data: While the raw data of the patient's IgG response results can be used to compare strength of response among given foods, it is also contemplated that the IgG response results of a patient are normalized and indexed to generate unit-less numbers for comparison of relative strength of response to a given food. For example, one or more of a patient's food specific IgG results (*e.g.,* IgG specific to orange and IgG specific to malt) can be normalized to the patient's total IgG. The normalized value of the patient's IgG specific to orange can be 0.1 and the normalized value of the patient's IgG specific to malt can be 0.3. In this scenario, the relative strength of the patient's response to malt is three times higher compared to orange. Then, the patient's sensitivity to malt and orange can be indexed as such.

[0097] In other examples, one or more of a patient's food specific IgG results (*e.g.,* IgG specific to shrimp and IgG specific to pork) can be normalized to the global mean of that patient's food specific IgG results. The global means of the patient's food specific IgG can be measured by total amount of the patient's food specific IgG. In this scenario, the patient's specific IgG to shrimp can be normalized to the mean of patient's total food specific IgG (*e.g.,* mean of IgG levels to shrimp, pork, Dungeness crab, chicken, peas, etc.) . However, it is also contemplated that the global means of the patient's food specific IgG can be measured by the patient's IgG levels to a specific type of food via multiple tests. If the patient have been tested for his sensitivity to shrimp five times and to pork seven times previously, the patient's new IgG values to shrimp or to pork are normalized to the mean of five-times test results to shrimp or the mean of seven-times test results to pork. The normalized value of the patient's IgG specific to shrimp can be 6.0 and the normalized value of the patient's IgG specific to pork can be 1.0. In this scenario, the patient has six times higher sensitivity to shrimp at this time compared to his average sensitivity to shrimp, but substantially similar sensitivity to pork. Then, the patient's sensitivity to shrimp and pork can be indexed based on such comparison.

[0098] Methodology to determine the subset of Functional Dyspepsia patients with food sensitivities that underlie Functional Dyspepsia: While it is suspected that food sensitivities plays a substantial role in signs and symptoms of Functional Dyspepsia, some Functional Dyspepsia patients may not have food sensitivities that underlie Functional Dyspepsia. Those patients would not be benefit from dietary intervention to treat signs and symptoms of Functional Dyspepsia. To determine the subset of such patients, body fluid samples of Functional Dyspepsia patients and non- Functional Dyspepsia patients can be tested with ELISA test using test devices with up to 37 food samples.

[0099] **Table 5A** and **Table 5B** provide exemplary raw data. As should be readily appreciated, the data indicate number of positive results out of 90 sample foods based on 90th percentile value (Table 5A) or 95th percentile value (Table 5B). The first column is Functional Dyspepsia (n=140); second column is non-Functional Dyspepsia (n=163) by ICD-10 code. Average and median number of positive foods was computed for Functional Dyspepsia and non-Functional Dyspepsia patients. From the raw data shown in Table 5A and Table 5B, average and standard deviation of the number of positive foods was computed for Functional Dyspepsia and non-Functional Dyspepsia patients. Additionally, the number and percentage of patients with zero positive foods was calculated for both Functional Dyspepsia and non-Functional Dyspepsia. The number and percentage of patients with zero positive foods in the migraine population is less than half of the percentage of patients with zero positive foods in the non-migraine population (17.9% vs. 39.3%, respectively) based on 90th percentile value (Table 5A), and the percentage of patients in the migraine population with zero positive foods is also approximately half of that seen in the non-Functional Dyspepsia population (30.7 % vs. 59.5%, respectively) based on 95th percentile value (Table 5B). Thus, it can be easily appreciated that the Functional Dyspepsia patient having sensitivity to zero positive foods is unlikely to have food sensitivities underlying their signs and symptoms of Functional Dyspepsia.

[00100] **Table 6A** and **Table 7A** show exemplary statistical data summarizing the raw data of two patient populations shown in Table 5A. The statistical data includes normality, arithmetic mean, median, percentiles and 95% confidence interval (CI) for the mean and median representing number of positive foods in the Functional Dyspepsia population and the non-Functional Dyspepsia population. **Table 6B** and **Table 7B** show exemplary statistical data summarizing the raw data of two patient populations shown in Table 5B. The statistical data includes normality, arithmetic mean, median, percentiles and 95% confidence interval (CI) for the mean and median representing number of positive foods in the Functional Dyspepsia population and the non-Functional Dyspepsia population.

[00101] **Table 8A** and **Table 9A** show exemplary statistical data summarizing the raw data of two patient populations shown in Table 5A. In Tables 8A and 9A, the raw data was transformed by logarithmic transformation to improve the data interpretation. **Table 8B** and **Table 9B** show another exemplary statistical data summarizing the raw data of two patient populations shown in Table 5B. In Tables 8B and 9B, the raw data was transformed by logarithmic transformation to improve the data interpretation.

[00102] **Table 10A** and **Table 11A** show exemplary statistical data of an independent T-test (Table 10A, logarithmically transformed data) and a Mann-Whitney test (Table 11A) to compare the geometric mean number of positive foods between the Functional Dyspepsia and non- Functional Dyspepsia samples. The data shown in Table 10A and Table 11A indicate statistically significant differences in the geometric mean of positive number of foods between the Functional Dyspepsia population and the non-Functional Dyspepsia population. In both statistical tests, it is shown that the number of positive responses with 37 food samples is significantly higher in the Functional Dyspepsia population than in the non-Functional Dyspepsia population with an average discriminatory p-value of ≤ 0.0001. These statistical data is also illustrated as a box and whisker plot in **Figure 6A**, and a notched box and whisker plot in **Figure 6B**.

[00103] **Table 10B** and **Table 11B** show exemplary statistical data of an independent T-test (Table 10A, logarithmically transformed data) and a Mann-Whitney test (Table 11B) to compare the geometric mean number of positive foods between the Functional Dyspepsia and non-Functional Dyspepsia samples. The data shown in Table 10B and Table 11B indicate statistically significant differences in the geometric mean of positive number of foods between the Functional Dyspepsia population and the non-Functional Dyspepsia population. In both statistical tests, it is shown that the number of positive responses with 37 food samples is significantly higher in the Functional Dyspepsia population than in the non-Functional Dyspepsia population with an average discriminatory p-value of ≤ 0.0001. These statistical data is also illustrated as a box and whisker plot in **Figure 6C**, and a notched box and whisker plot in **Figure 6D**.

[00104] **Table 12A** shows exemplary statistical data of a Receiver Operating Characteristic (ROC) curve analysis of data shown in Tables 5A-11A to determine the diagnostic power of the test used in Table 5 at discriminating Functional Dyspepsia from non- Functional Dyspepsia subjects. When a cutoff criterion of more than 1 positive food is used, the test yields a data with 72.9% sensitivity and 60.1% specificity, with an area under the curve (AUROC) of 0.688. The p-value for the ROC is significant at a p-value of <0.0001. **Figure 7A** illustrates the ROC curve corresponding to the statistical data shown in Table 12A. Because the statistical difference between the Functional Dyspepsia population and the non-Functional Dyspepsia population is significant when the test results are cut off to a positive number of 1, the number of foods for which a patient tests positive could be used as a confirmation of the primary clinical diagnosis of Functional Dyspepsia, and whether it is likely that food sensitivities underlies on the patient’s signs and symptoms of Functional Dyspepsia. Therefore, the above test can be used as another ‘rule in’ test to add to currently available clinical criteria for diagnosis for Functional Dyspepsia.

[00105] As shown in Tables 5A-12A, and Figure 7A, based on 90^{th} percentile data, the number of positive foods seen in Functional Dyspepsia vs. non-Functional Dyspepsia subjects is significantly different whether the geometric mean or median of the data is compared. The number of positive foods that a person has is indicative of the presence of Functional Dyspepsias in subjects. The test has discriminatory power to detect Functional Dyspepsia with ~73% sensitivity and ~60% specificity. Additionally, the absolute number and percentage of subjects with 0 positive foods is also very different in Functional Dyspepsia vs. non-Functional Dyspepsia subjects, with a far lower percentage of Functional Dyspepsia subjects (17.9%) having 0 positive foods than non-Functional Dyspepsia subjects (39.3%). The data suggests a subset of Functional Dyspepsia patients may have Functional Dyspepsia due to other factors than diet, and may not benefit from dietary restriction.

[00106] **Table 12B** shows exemplary statistical data of a Receiver Operating Characteristic (ROC) curve analysis of data shown in Tables 5B-11B to determine the diagnostic power of the test used in Table 5 at discriminating Functional Dyspepsia from non-Functional Dyspepsia subjects. When a cutoff criterion of more than 1 positive foods is used, the test yields a data with 69.3% sensitivity and 59.5% specificity, with an area under the curve (AUROC) of 0.686. The p-value for the ROC is significant at a p-value of <0.0001. **Figure 7B** illustrates the ROC curve corresponding to the statistical data shown in Table 12B. Because the statistical difference between the Functional Dyspepsia population and the non-Functional Dyspepsia population is significant when the test results are cut off to positive number of >0, the number of foods that a patient tests positive could be used as a confirmation of the primary clinical diagnosis of Functional Dyspepsia, and whether it is likely that food sensitivities underlies on the patient's signs and symptoms of Functional Dyspepsia. Therefore, the above test can be used as another 'rule in' test to add to currently available clinical criteria for diagnosis for Functional Dyspepsia.

[00107] As shown in Tables 5B-12B, and Figure 7B, based on 95th percentile data, the number of positive foods seen in Functional Dyspepsia vs. non-Functional Dyspepsia subjects is significantly different whether the geometric mean or median of the data is compared. The number of positive foods that a person has is indicative of the presence of Functional Dyspepsia in subjects. The test has discriminatory power to detect Functional Dyspepsia with ~69% sensitivity and ~60% specificity. Additionally, the absolute number and percentage of subjects with 0 positive foods is also very different in Functional Dyspepsia vs. non-Functional Dyspepsia subjects, with a far lower percentage of Functional Dyspepsia subjects (~31%) having 0 positive foods than non- Functional Dyspepsia subjects (~60%). The data suggests a subset of Functional Dyspepsia patients may have Functional Dyspepsia due to other factors than diet, and may not benefit from dietary restriction.

[00108] <u>Method for determining distribution of per-person number of foods declared "positive"</u>: To determine the distribution of number of "positive" foods per person and measure the diagnostic performance, the analysis will be performed with 37 food items from Table 2, which shows most positive responses to Functional Dyspepsia patients. To attenuate the influence of any one subject on this analysis, each food-specific and gender-specific dataset will be bootstrap resampled 1000 times. Then, for each food item in the bootstrap sample, sex-specific cutpoint will be determined using the 90th and 95th percentiles of the control population. Once the sex-specific cutpoints are determined, the sex-specific cutpoints will be compared with the observed ELISA signal scores for both control and Functional Dyspepsia subjects. In this comparison, if the observed signal is equal or more than the cutpoint value, then it will be determined "positive" food, and if the observed signal is less than the cutpoint value, then it will be determined "negative" food.

[00109] Once all food items were determined either positive or negative, the results of the 74(37 foods x 2 cutpoints) calls for each subject will be saved within each bootstrap replicate. Then, for each subject, 37 calls will be summed using 90^{th} percentile as cutpoint to get "Number of Positive Foods (90^{th})," and the rest of 37 calls will be summed using 95^{th} percentile to get "Number of Positive Foods (95^{th})." Then, within each replicate, "Number of Positive Foods (90^{th})" and "Number of Positive Foods (95^{th})" will be summarized across subjects to get descriptive statistics for each replicate as follows: 1) overall means equals to the mean of means, 2) overall standard deviation equals to the mean of standard deviations, 3) overall medial equals to the mean of medians, 4) overall minimum equals to the minimum of minimums, and 5) overall maximum equals to maximum of maximum. In this analysis, to avoid non-integer "Number of Positive Foods" when computing frequency distribution and histogram, the authors will pretend that the 1000 repetitions of the same original dataset were actually 999 sets of new subjects of the same size added to the original sample. Once the summarization of data is done, frequency distributions and histograms will be generated for both "Number of Positive Foods (90^{th})" and "Number of Positive Foods (95^{th})" for both genders and for both Functional Dyspepsia subjects and control subjects using programs "a_pos_foods.sas, a_pos_foods_by_dx.sas".

[00110] <u>Method for measuring diagnostic performance</u>: To measure diagnostic performance for each food items for each subject, we will use data of "Number of Positive Foods (90^{th})" and "Number of Positive Foods (95^{th})" for each subject within each bootstrap replicate described above. In this analysis, the cutpoint was set to 1. Thus, if a subject has one or more "Number of Positive Foods (90^{th})", then the subject will be called "Has Functional Dyspepsia." If a subject has less than one "Number of Positive Foods (90^{th})", then the subject will be called "Does Not Have Functional Dyspepsia." When all calls were made, the calls were compared with actual diagnosis to determine whether a call was a True Positive (TP), True Negative (TN), False Positive(FP), or False Negative(FN). The comparisons will be summarized across subjects to get the performance metrics of sensitivity, specificity, positive predictive value, and negative predictive value for both "Number of Positive Foods (90^{th})" and "Number of Positive Foods(95^{th})" when the cutpoint is set to 1 for each method. Each (sensitivity, 1-specificity) pair becomes a point on the ROC curve for this replicate.

[00111] To increase the accuracy, the analysis above will be repeated by incrementing cutpoint from 2 up to 37, and repeated for each of the 1000 bootstrap replicates. Then the performance metrics across the 1000 bootstrap replicates will be summarized by calculating averages using a program “t_pos_foods_by_dx.sas”. The results of diagnostic performance for female and male are shown in **Tables 13A and 13B** (90th percentile) and **Tables 14 A and 14B** (95th percentile).

[00112] Of course, it should be appreciated that certain variations in the food preparations may be made without altering the inventive subject matter presented herein. For example, where the food item was yellow onion, that item should be understood to also include other onion varieties that were demonstrated to have equivalent activity in the tests. Indeed, the inventors have noted that for each tested food preparation, certain other related food preparations also tested in the same or equivalent manner (data not shown). Thus, it should be appreciated that each tested and claimed food preparation will have equivalent related preparations with demonstrated equal or equivalent reactions in the test.

[00113] It should be apparent to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the spirit of the appended claims. Moreover, in interpreting both the specification and the claims, all terms should be interpreted in the broadest possible manner consistent with the context. In particular, the terms “comprises” and “comprising” should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced. Where the specification claims refers to at least one of something selected from the group consisting of A, B, C …. and N, the text should be interpreted as requiring only one element from the group, not A plus N, or B plus N, etc.

CLAIMS

What is claimed is:

1. A test kit for testing food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia, comprising:

    one or more distinct food preparations, wherein each food preparation is independently coupled to an individually addressable solid carrier;

    wherein each distinct food preparation has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value, or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value, wherein the average discriminatory p-value is determined by a process comprising comparing assay values of a first patient test cohort that is diagnosed with or suspected of having Functional Dyspepsia with assay values of a second patient test cohort that is not diagnosed with or suspected of having Functional Dyspepsia.

2. The test kit of claim 1 wherein the plurality of food preparations includes at least two food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

3. The test kit of claim 1 wherein the plurality of food preparations includes at least four food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

4. The test kit of claim 1 wherein the plurality of food preparations includes at least eight food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

5. The test kit of claim 1 wherein the plurality of food preparations includes at least 12 food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

6. The test kit of claim 1 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

7. The test kit of any one of claims 1-5 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an

average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

8. The test kit of claim 1 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

9. The test kit of any one of claims 1-5 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

10. The test kit of claim 1 wherein FDR multiplicity adjusted p-value is adjusted for at least one of age and gender.

11. The test kit of any one of claims 1-8 wherein FDR multiplicity adjusted p-value is adjusted for at least one of age and gender.

12. The test kit of claim 1 wherein FDR multiplicity adjusted p-value is adjusted for age and gender.

13. The test kit of any one of claims 1-8 wherein FDR multiplicity adjusted p-value is adjusted for age and gender.

14. The test kit of claim 1 wherein at least 50% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

15. The test kit of any one of claims 1-13 wherein at least 50% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

16. The test kit of claim 1 wherein at least 70% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as

determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

17. The test kit of any one of the claims 1-13 wherein at least 70% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

18. The test kit of claim 1 wherein all of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

19. The test kit of any one of the claims 1-17 wherein all of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

20. The test kit of claim 1 wherein the plurality of distinct food preparations is crude filtered aqueous extracts.

21. The test kit of any one of the claims 1-19 wherein the plurality of distinct food preparations is crude filtered aqueous extracts.

22. The test kit of claim 1 wherein the plurality of distinct food preparations is processed aqueous extracts.

23. The test kit of any one of the claims 1-21 wherein the plurality of distinct food preparations is processed aqueous extracts.

24. The test kit of claim 1 wherein the solid carrier is a well of a multiwall plate, a bead, an electrical, a chemical sensor, a microchip or an adsorptive film.

25. The test kit of any one of the claims 1-23 wherein the solid carrier is a well of a multiwall plate, a bead, an electrical, a chemical sensor, a microchip or an adsorptive film.

26. A method of testing food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia, comprising:

contacting a food preparation with a bodily fluid of a patient that is diagnosed with or suspected to have Functional Dyspepsia, and wherein the bodily fluid is associated with a gender identification;

wherein the step of contacting is performed under conditions that allow IgG from the bodily fluid to bind to at least one component of the food preparation;

measuring IgG bound to the at least one component of the food preparation to obtain a signal;

comparing the signal to a gender-stratified reference value for the food preparation using the gender identification to obtain a result; and

updating or generating a report using the result.

27. The method of claim 26 wherein the bodily fluid of the patient is whole blood, plasma, serum, saliva, or a fecal suspension.

28. The method of claim 26 wherein the step of contacting a food preparation is performed with a plurality of distinct food preparations.

29. The method of claim 26 or claim 27 wherein the step of contacting a food preparation is performed with a plurality of distinct food preparations.

30. The method of claim 28 wherein the plurality of distinct food preparations is prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

31. The method of any of the claims 28-29 wherein the plurality of distinct food preparations is prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

32. The method of claim 28 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

33. The method of any of the claims 28-29 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

34. The method of claim 28 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

35. The method of any of the claims 28-29 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

36. The method of claim 28 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

37. The method of any of the claims 28-29 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

38. The method of claim 28 wherein all of the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

39. The method of any of the claims 28-29 wherein all of the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

40. The method of claim 26 wherein the food preparation is immobilized on a solid surface, optionally in an addressable manner.

41. The method of any of the claims 26-39 wherein the food preparation is immobilized on a solid surface, optionally in an addressable manner.

42. The method of claim 26 wherein the step of measuring IgG bound to the at least one component of the food preparation is performed via an immunoassay test.

43. The method of any of the claims 26-41 wherein the step of measuring IgG bound to the at least one component of the food preparation is performed via immunoassay test.

44. The method of claim 26 wherein the gender-stratified reference value for the food preparation is an at least a 90^{th} percentile value.

45. The method of any of the claims 26-43 wherein the gender-stratified reference value for the food preparation is an at least a 90^{th} percentile value.

46. A method of generating a test for food intolerance in patients diagnosed with or suspected to have Functional Dyspepsia, comprising:

    obtaining test results for a plurality of distinct food preparations, wherein the test results are based on bodily fluids of patients diagnosed with or suspected to have Functional Dyspepsia and bodily fluids of a control group not diagnosed with or not suspected to have Functional Dyspepsia;

    stratifying the test results by gender for each of the distinct food preparations; and

    assigning for a predetermined percentile rank a different cutoff value for male and female patients for each of the distinct food preparations.

47. The method of claim 46 wherein the test result is an ELISA result.

48. The method of claim 46 wherein the plurality of distinct food preparations includes at least two food preparations prepared from food items of Table 1 or selected foods 1-37 of Table 2.

49. The method of claim 46 or claim 47 wherein the plurality of distinct food preparations includes at least two food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

50. The method of claim 46 wherein the plurality of distinct food preparations includes at least six food preparations prepared from food items of Table 1 or selected from a group consisting of foods 1-37 of Table 2.

51. The method of any of claim 46 or claim 47 wherein the plurality of distinct food preparations includes at least six food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

52. The method of claim 46 wherein the plurality of distinct food preparations includes a food preparation prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

53. The method of any of claim 46 or 47 wherein the plurality of distinct food preparations includes a food preparation prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

54. The method of claim 46 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

55. The method of any of claims 46-53 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

56. The method of claim 46 wherein the plurality of different food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

57. The method of any of claims 46-53 wherein the plurality of different food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

58. The method of claim 46 wherein the plurality of different food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

59. The method of any of claims 46-53 wherein the plurality of different food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

60. The method of claim 46 wherein the bodily fluid of the patient is whole blood, plasma, serum, saliva, or a fecal suspension.

61. The method of any of claims 46-59 wherein the bodily fluid of the patient is whole blood, plasma, serum, saliva, or a fecal suspension.

62. The method of claim 46 wherein the predetermined percentile rank is an at least 90^{th} percentile rank.

63. The method of any of claims 46-61 wherein the predetermined percentile rank is an at least 90^{th} percentile rank.

64. The method of claim 46 wherein the cutoff value for male and female patients has a difference of at least 10% (abs).

65. The method of any of claims 46-63 wherein the cutoff value for male and female patients has a difference of at least 10% (abs).

66. The method of claim 26 or 46, further comprising a step of normalizing the result to the patient's total IgG.

67. The method of any of claims 26-65, further comprising a step of normalizing the result to the patient's total IgG.

68. The method of claim 26 or 46, further comprising a step of normalizing the result to the global mean of the patient's food specific IgG results.

69. The method of any of claims 26-65, further comprising a step of normalizing the result to the global mean of the patient's food specific IgG results.

70. The method of claim 26 or 46, further comprising a step of identifying a subset of patients, wherein the subset of patients' sensitivities to the food preparations underlies Functional Dyspepsia by raw p-value or an average discriminatory p-value of ≤ 0.01.

71. The method of any of claims 26-65, further comprising a step of identifying a subset of patients, wherein the subset of patients' sensitivities to the food preparations underlies Functional Dyspepsia by raw p-value or an average discriminatory p-value of ≤ 0.01.

72. The method of claim 26 or 46, further comprising a step of determining numbers of the food preparations, wherein the numbers of the food preparations can be used to confirm Functional Dyspepsia by raw p-value or an average discriminatory p-value of ≤ 0.01.

73. The method of any of claims 26-65, further comprising a step of determining numbers of the food preparations, wherein the numbers of the food preparations can be used to confirm Functional Dyspepsia by raw p-value or an average discriminatory p-value of ≤ 0.01.

74. Use of a plurality of distinct food preparations coupled to individually addressable respective solid carriers in a diagnosis of Functional Dyspepsia, wherein the plurality of distinct food preparations have an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

75. Use of claim 74 wherein the plurality of food preparations includes at least two food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

76. Use of claim 74 wherein the plurality of food preparations includes at least four food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

77. Use of claim 74 wherein the plurality of food preparations includes at least eight food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

78. Use of claim 74 wherein the plurality of food preparations includes at least 12 food preparations prepared from food items of Table 1 or selected from foods 1-37 of Table 2.

79. Use of claim 74 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

80. Use of any one of claims 74-78, wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.05 as determined by raw p-value or an average discriminatory p-value of ≤ 0.08 as determined by FDR multiplicity adjusted p-value.

81. Use of claim of claim 74 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

82. Use of any one of claims 74-78 wherein the plurality of distinct food preparations has an average discriminatory p-value of ≤ 0.025 as determined by raw p-value or an average discriminatory p-value of ≤ 0.07 as determined by FDR multiplicity adjusted p-value.

83. Use of claim 74 wherein FDR multiplicity adjusted p-value is adjusted for at least one of age and gender.

84. Use of any one of claims 74-82 wherein FDR multiplicity adjusted p-value is adjusted for at least one of age and gender.

85. Use of claim 74 wherein FDR multiplicity adjusted p-value is adjusted for age and gender.

86. Use of any one of claims 74-82 wherein FDR multiplicity adjusted p-value is adjusted for age and gender.

87. Use of claim 74 wherein at least 50% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

88. Use of any one of claims 74-86 wherein at least 50% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

89. Use of claim 74 wherein at least 70% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

90. Use of any one of the claims 74-86 wherein at least 70% of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

91. Use of claim 74 wherein all of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

92. Use of any one of the claims 74-86 wherein all of the plurality of distinct food preparations, when adjusted for a single gender, has an average discriminatory p-value of ≤ 0.07 as determined by raw p-value or an average discriminatory p-value of ≤ 0.10 as determined by FDR multiplicity adjusted p-value.

93. Use of claim 74 wherein the plurality of distinct food preparations is crude filtered aqueous extracts.

94. Use of any one of the claims 74-92 wherein the plurality of distinct food preparations is crude filtered aqueous extracts.

95. Use of claim 74 wherein the plurality of distinct food preparations is processed aqueous extracts.

96. Use of any one of the claims 74-94 wherein the plurality of distinct food preparations is processed aqueous extracts.

97. Use of claim 74 wherein the solid carrier is a well of a multiwall plate, a bead, an electrical sensor, a chemical sensor, a microchip, or an adsorptive film.

98. Use of any one of the claims 74-96 wherein the solid carrier is a well of a multiwall plate, a bead, an electrical sensor, a chemical sensor, a microchip, or an adsorptive film.

99. Use of any one of claims 74-96, wherein the average discriminatory p-value is determined by a process comprising comparing assay values of a first patient test cohort that is diagnosed with or suspected of having migraine headaches with assay values of a second patient test cohort that is not diagnosed with or suspected of having migraine headaches.

100. The method of claim 46, wherein the test result is an ELISA result derived from a process that includes separately contacting each distinct food preparation with the bodily fluid of each patient.

Abalone	Cured Cheese	Onion	Walnut, black
Adlay	Cuttlefish	Orange	Watermelon
Almond	Duck	Oyster	Welch Onion
American Cheese	Durian	Papaya	Wheat
Apple	Eel	Paprika	Wheat bran
Artichoke	Egg White (separate)	Parsley	Yeast (S. cerevisiae)
Asparagus	Egg Yolk (separate)	Peach	Yogurt
Avocado	Egg, white/yolk (comb.)	Peanut	
Baby Bok Choy	Eggplant	Pear	**FOOD ADDITIVES**
Bamboo shoots	Garlic	Pepper, Black	Arabic Gum
Banana	Ginger	Pineapple	Carboxymethyl Cellulose
Barley, whole grain	Gluten - Gliadin	Pinto bean	Carrageneenan
Beef	Goat's milk	Plum	FD&C Blue #1
Beets	Grape, white/concord	Pork	FD&C Red #3
Beta-lactoglobulin	Grapefruit	Potato	FD&C Red #40
Blueberry	Grass Carp	Rabbit	FD&C Yellow #5
Broccoli	Green Onion	Rice	FD&C Yellow #6
Buckwheat	Green pea	Roquefort Cheese	Gelatin
Butter	Green pepper	Rye	Guar Gum
Cabbage	Guava	Saccharine	Maltodextrin
Cane sugar	Hair Tail	Safflower seed	Pectin
Cantaloupe	Hake	Salmon	Whey
Caraway	Halibut	Sardine	Xanthan Gum
Carrot	Hazelnut	Scallop	
Casein	Honey	Sesame	
Cashew	Kelp	Shark fin	
Cauliflower	Kidney bean	Sheep's milk	
Celery	Kiwi Fruit	Shrimp	
Chard	Lamb	Sole	
Cheddar Cheese	Leek	Soybean	
Chick Peas	Lemon	Spinach	
Chicken	Lentils	Squashes	
Chili pepper	Lettuce, Iceberg	Squid	
Chocolate	Lima bean	Strawberry	
Cinnamon	Lobster	String bean	
Clam	Longan	Sunflower seed	
Cocoa Bean	Mackerel	Sweet potato	
Coconut	Malt	Swiss cheese	
Codfish	Mango	Taro	
Coffee	Marjoram	Tea, black	
Cola nut	Millet	Tobacco	
Corn	Mung bean	Tomato	
Cottage cheese	Mushroom	Trout	
Cow's milk	Mustard seed	Tuna	
Crab	Oat	Turkey	
Cucumber	Olive	Vanilla	

Table 1

Ranking of Foods according to 2-tailed Permutation T-test p-values with FDR adjustment

Rank	*Food*	*Raw p-value*	*FDR Multiplicity-adj p-value*
1	Orange	0.0000	0.0000
2	Barley	0.0001	0.0036
3	Oat	0.0001	0.0036
4	Malt	0.0002	0.0036
5	Rye	0.0002	0.0036
6	Almond	0.0002	0.0036
7	Butter	0.0004	0.0046
8	Chocolate	0.0005	0.0056
9	Cottage_Ch_	0.0008	0.0083
10	Cow_Milk	0.0009	0.0083
11	Cola_Nut	0.0011	0.0087
12	Cucumber	0.0016	0.0101
13	Amer__Cheese	0.0016	0.0101
14	Tobacco	0.0017	0.0101
15	Cheddar_Ch_	0.0017	0.0101
16	Green_Pea	0.0025	0.0138
17	Walnut_Blk	0.0039	0.0205
18	Swiss_Ch_	0.0046	0.0228
19	Wheat	0.0048	0.0228
20	Cane_Sugar	0.0060	0.0271
21	Sunflower_Sd	0.0069	0.0296
22	Mustard	0.0085	0.0348
23	Yeast_Brewer	0.0090	0.0348
24	Yeast_Baker	0.0093	0.0348
25	Cinnamon	0.0126	0.0452
26	Cauliflower	0.0151	0.0524
27	Yogurt	0.0196	0.0655
28	Grapefruit	0.0225	0.0725
29	Cantaloupe	0.0242	0.0752
30	Green_Pepper	0.0276	0.0828
31	Egg	0.0290	0.0841
32	String_Bean	0.0303	0.0853

Rank	Food	Raw p-value	FDR Multiplicity-adj p-value
33	Broccoli	0.0340	0.0928
34	Buck_Wheat	0.0359	0.0950
35	Cabbage	0.0373	0.0959
36	Corn	0.0404	0.0989
37	Honey	0.0406	0.0989
38	Goat_Milk	0.0568	0.1344
39	Rice	0.0752	0.1734
40	Pineapple	0.0813	0.1828
41	Lemon	0.0846	0.1857
42	Carrot	0.0872	0.1869
43	Oyster	0.0999	0.2090
44	Peanut	0.1056	0.2160
45	Tomato	0.1160	0.2291
46	Safflower	0.1187	0.2291
47	Parsley	0.1197	0.2291
48	Clam	0.1222	0.2291
49	Trout	0.1276	0.2324
50	Celery	0.1291	0.2324
51	Soybean	0.1491	0.2631
52	Cashew	0.1549	0.2680
53	Onion	0.1713	0.2909
54	Mushroom	0.1894	0.3156
55	Avocado	0.2028	0.3319
56	Lima_Bean	0.2159	0.3401
57	Tea	0.2185	0.3401
58	Sardine	0.2222	0.3401
59	Chicken	0.2230	0.3401
60	Garlic	0.2490	0.3734
61	Squashes	0.2820	0.4161
62	Apple	0.3270	0.4746
63	Beef	0.3453	0.4908
64	Sweet_Pot_	0.3490	0.4908
65	Spinach	0.3818	0.5287
66	Banana	0.4097	0.5582
67	Eggplant	0.4156	0.5582
68	Sesame	0.4643	0.6145
69	Turkey	0.4749	0.6194

Rank	*Food*	*Raw p-value*	*FDR Multiplicity-adj p-value*
70	Millet	0.5272	0.6778
71	Olive	0.6099	0.7619
72	Salmon	0.6145	0.7619
73	Pork	0.6259	0.7619
74	Sole	0.6264	0.7619
75	Lettuce	0.6521	0.7822
76	Grape	0.6827	0.7822
77	Lobster	0.6835	0.7822
78	Potato	0.6857	0.7822
79	Crab	0.6866	0.7822
80	Pinto_Bean	0.7652	0.8608
81	Coffee	0.7806	0.8673
82	Halibut	0.7984	0.8763
83	Blueberry	0.8716	0.9452
84	Codfish	0.9052	0.9699
85	Scallop	0.9470	0.9914
86	Chili_Pepper	0.9547	0.9914
87	Shrimp	0.9583	0.9914
88	Strawberry	0.9885	0.9964
89	Tuna	0.9912	0.9964
90	Peach	0.9964	0.9964

Table 2

Basic Descriptive Statistics of ELISA Score by Food and Gender Comparing Functional Dyspepsia to Control

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
FEMALE	Almond	Dyspeptic	71	8.413	14.078	0.510	89.369
		Control	66	4.034	2.187	0.100	13.068
		Diff (1-2)	_	4.379	10.250	_	_
	Amer__Cheese	Dyspeptic	71	48.084	78.219	2.092	399.29
		Control	66	23.434	52.616	0.100	400.00
		Diff (1-2)	_	24.650	67.122	_	_
	Apple	Dyspeptic	71	5.302	5.480	0.593	37.022
		Control	66	4.432	3.291	0.100	15.890
		Diff (1-2)	_	0.870	4.559	_	_
	Avocado	Dyspeptic	71	3.479	4.438	0.100	35.259
		Control	66	2.930	2.339	0.100	14.256
		Diff (1-2)	_	0.548	3.585	_	_
	Banana	Dyspeptic	71	12.022	23.692	0.528	134.61
		Control	66	8.063	14.962	0.100	83.654
		Diff (1-2)	_	3.959	19.971	_	_
	Barley	Dyspeptic	71	25.884	20.590	2.120	116.51
		Control	66	19.090	12.984	3.026	64.831
		Diff (1-2)	_	6.794	17.349	_	_
	Beef	Dyspeptic	71	10.212	10.447	1.432	54.607
		Control	66	10.288	13.960	3.026	104.76
		Diff (1-2)	_	-0.077	12.264	_	_
	Blueberry	Dyspeptic	71	5.616	6.863	0.497	52.021
		Control	66	5.440	3.773	0.100	26.772
		Diff (1-2)	_	0.176	5.593	_	_
	Broccoli	Dyspeptic	71	8.955	10.894	0.892	79.868
		Control	66	6.280	5.292	0.100	36.378
		Diff (1-2)	_	2.675	8.661	_	_
	Buck_Wheat	Dyspeptic	71	8.362	5.176	1.890	24.216
		Control	66	8.034	4.990	1.316	29.397
		Diff (1-2)	_	0.328	5.087	_	_
	Butter	Dyspeptic	71	34.690	39.954	1.286	198.30
		Control	66	21.874	29.162	0.100	204.33
		Diff (1-2)	_	12.817	35.174	_	_
	Cabbage	Dyspeptic	71	11.154	14.794	0.099	72.583

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
		Control	66	7.362	10.123	0.100	56.932
		Diff (1-2)	_	3.791	12.760	_	_
	Cane_Sugar	Dyspeptic	71	28.488	21.215	1.978	129.15
		Control	66	18.288	9.172	2.632	43.466
		Diff (1-2)	_	10.200	16.549	_	_
	Cantaloupe	Dyspeptic	71	8.391	8.260	0.890	38.510
		Control	66	6.154	6.160	0.100	48.752
		Diff (1-2)	_	2.237	7.324	_	_
	Carrot	Dyspeptic	71	6.062	7.606	0.119	52.139
		Control	66	4.813	3.705	0.100	24.141
		Diff (1-2)	_	1.249	6.050	_	_
	Cashew	Dyspeptic	71	19.679	66.017	0.791	400.00
		Control	66	9.924	16.382	0.100	94.907
		Diff (1-2)	_	9.756	48.878	_	_
	Cauliflower	Dyspeptic	71	8.104	10.581	0.100	72.464
		Control	66	5.977	8.336	0.100	58.808
		Diff (1-2)	_	2.127	9.566	_	_
	Celery	Dyspeptic	71	11.281	11.836	1.656	72.345
		Control	66	9.634	5.975	0.395	32.141
		Diff (1-2)	_	1.648	9.478	_	_
	Cheddar_Ch_	Dyspeptic	71	56.766	94.788	0.264	400.00
		Control	66	26.852	55.697	0.100	400.00
		Diff (1-2)	_	29.914	78.437	_	_
	Chicken	Dyspeptic	71	17.783	17.751	3.066	133.99
		Control	66	18.303	10.514	4.743	61.887
		Diff (1-2)	_	-0.520	14.718	_	_
	Chili_Pepper	Dyspeptic	71	8.958	9.532	0.835	63.952
		Control	66	8.577	7.784	0.100	42.583
		Diff (1-2)	_	0.382	8.734	_	_
	Chocolate	Dyspeptic	71	21.176	14.281	4.176	61.062
		Control	66	14.350	6.578	3.006	35.317
		Diff (1-2)	_	6.826	11.251	_	_
	Cinnamon	Dyspeptic	71	38.068	32.132	2.967	151.87
		Control	66	32.170	24.180	5.374	132.49
		Diff (1-2)	_	5.898	28.581	_	_
	Clam	Dyspeptic	71	36.012	29.408	2.769	144.02
		Control	66	52.166	58.253	7.819	400.00

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
		Diff (1-2)	_	-16.154	45.632	_	_
	Codfish	Dyspeptic	71	17.111	14.346	3.382	73.038
		Control	66	29.652	31.720	6.200	168.28
		Diff (1-2)	_	-12.541	24.313	_	_
	Coffee	Dyspeptic	71	30.140	48.986	1.187	252.24
		Control	66	29.631	46.880	5.215	346.81
		Diff (1-2)	_	0.509	47.983	_	_
	Cola_Nut	Dyspeptic	71	36.180	19.285	3.462	98.192
		Control	66	29.138	12.588	8.723	58.129
		Diff (1-2)	_	7.042	16.406	_	_
	Corn	Dyspeptic	71	17.200	26.502	0.497	122.15
		Control	66	11.407	23.137	0.100	187.68
		Diff (1-2)	_	5.793	24.939	_	_
	Cottage_Ch_	Dyspeptic	71	133.197	138.198	1.088	400.00
		Control	66	76.158	92.333	0.100	400.00
		Diff (1-2)	_	57.039	118.355	_	_
	Cow_Milk	Dyspeptic	71	124.401	131.331	0.262	400.00
		Control	66	75.882	86.959	0.100	400.00
		Diff (1-2)	_	48.518	112.180	_	_
	Crab	Dyspeptic	71	18.397	16.181	1.187	92.728
		Control	66	23.583	17.654	3.803	93.236
		Diff (1-2)	_	-5.186	16.906	_	_
	Cucumber	Dyspeptic	71	16.832	26.388	0.398	152.49
		Control	66	8.461	8.149	0.100	38.939
		Diff (1-2)	_	8.371	19.825	_	_
	Egg	Dyspeptic	71	87.893	128.533	0.692	400.00
		Control	66	55.102	89.966	0.100	400.00
		Diff (1-2)	_	32.791	111.639	_	_
	Eggplant	Dyspeptic	71	7.972	15.029	0.100	116.40
		Control	66	5.732	5.993	0.100	31.330
		Diff (1-2)	_	2.239	11.593	_	_
	Garlic	Dyspeptic	71	16.417	15.435	1.286	92.987
		Control	66	11.174	5.779	3.380	28.482
		Diff (1-2)	_	5.242	11.815	_	_
	Goat_Milk	Dyspeptic	71	27.659	48.614	0.593	298.62
		Control	66	15.413	28.452	0.100	180.08
		Diff (1-2)	_	12.245	40.190	_	_

Sex	*Food*	*Diagnosis*	*N*	*ELISA Score* *Mean*	*SD*	*Min*	*Max*
	Grape	Dyspeptic	71	23.794	41.105	3.780	342.78
		Control	66	20.276	6.827	10.650	47.817
		Diff (1-2)	_	3.519	29.975	_	_
	Grapefruit	Dyspeptic	71	4.698	7.252	0.100	56.874
		Control	66	3.278	2.446	0.100	14.364
		Diff (1-2)	_	1.420	5.491	_	_
	Green_Pea	Dyspeptic	71	13.217	13.524	0.558	69.056
		Control	66	8.631	7.160	0.496	32.502
		Diff (1-2)	_	4.586	10.932	_	_
	Green_Pepper	Dyspeptic	71	6.548	13.194	0.100	108.22
		Control	66	4.149	2.875	0.100	14.364
		Diff (1-2)	_	2.399	9.708	_	_
	Halibut	Dyspeptic	71	10.658	8.835	2.077	67.987
		Control	66	11.119	7.129	2.729	44.884
		Diff (1-2)	_	-0.461	8.059	_	_
	Honey	Dyspeptic	71	12.745	8.024	3.165	44.968
		Control	66	10.185	4.203	4.227	19.876
		Diff (1-2)	_	2.560	6.472	_	_
	Lemon	Dyspeptic	71	3.004	3.671	0.100	28.010
		Control	66	2.482	2.159	0.100	14.688
		Diff (1-2)	_	0.522	3.038	_	_
	Lettuce	Dyspeptic	71	11.102	13.354	0.995	106.60
		Control	66	11.368	6.472	0.921	29.851
		Diff (1-2)	_	-0.266	10.613	_	_
	Lima_Bean	Dyspeptic	71	6.947	6.169	0.298	34.717
		Control	66	6.624	8.761	0.100	65.634
		Diff (1-2)	_	0.323	7.529	_	_
	Lobster	Dyspeptic	71	9.923	7.022	1.193	37.144
		Control	66	13.398	8.359	3.938	46.560
		Diff (1-2)	_	-3.475	7.695	_	_
	Malt	Dyspeptic	71	28.582	15.173	3.382	63.777
		Control	66	21.743	11.326	3.684	57.151
		Diff (1-2)	_	6.839	13.459	_	_
	Millet	Dyspeptic	71	3.677	3.304	0.199	22.101
		Control	66	4.889	7.091	0.100	46.663
		Diff (1-2)	_	-1.212	5.465	_	_
	Mushroom	Dyspeptic	71	11.843	15.247	0.398	100.59

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
		Control	66	13.174	12.549	1.117	49.656
		Diff (1-2)	_	-1.330	14.013	_	_
	Mustard	Dyspeptic	71	11.041	8.913	0.989	40.833
		Control	66	8.842	5.224	0.100	23.452
		Diff (1-2)	_	2.198	7.371	_	_
	Oat	Dyspeptic	71	39.263	39.193	0.696	181.43
		Control	66	16.237	14.506	0.100	76.165
		Diff (1-2)	_	23.026	29.964	_	_
	Olive	Dyspeptic	71	23.542	18.903	1.582	89.038
		Control	66	23.704	14.281	5.272	59.488
		Diff (1-2)	_	-0.162	16.837	_	_
	Onion	Dyspeptic	71	17.888	48.019	0.791	400.00
		Control	66	11.329	16.935	1.184	114.37
		Diff (1-2)	_	6.559	36.520	_	_
	Orange	Dyspeptic	71	32.891	39.959	1.492	261.86
		Control	66	15.289	11.608	1.489	47.125
		Diff (1-2)	_	17.602	29.880	_	_
	Oyster	Dyspeptic	71	54.663	62.122	2.275	400.00
		Control	66	42.674	33.485	5.656	168.59
		Diff (1-2)	_	11.989	50.407	_	_
	Parsley	Dyspeptic	71	8.747	16.093	0.100	103.11
		Control	66	5.005	6.541	0.100	34.932
		Diff (1-2)	_	3.742	12.445	_	_
	Peach	Dyspeptic	71	8.523	10.797	0.298	47.376
		Control	66	7.145	7.742	0.100	33.820
		Diff (1-2)	_	1.378	9.450	_	_
	Peanut	Dyspeptic	71	7.245	17.873	0.100	147.33
		Control	66	5.563	4.941	0.100	26.567
		Diff (1-2)	_	1.682	13.319	_	_
	Pineapple	Dyspeptic	71	42.542	69.029	0.298	379.71
		Control	66	23.710	46.114	0.100	278.44
		Diff (1-2)	_	18.832	59.116	_	_
	Pinto_Bean	Dyspeptic	71	9.187	8.527	0.510	47.514
		Control	66	10.138	8.167	0.100	48.623
		Diff (1-2)	_	-0.951	8.356	_	_
	Pork	Dyspeptic	71	16.598	24.700	2.089	165.08
		Control	66	15.347	10.345	4.339	65.759

Sex	Food	Diagnosis	N	ELISA Score Mean	SD	Min	Max
		Diff (1-2)	_	1.251	19.180	_	_
	Potato	Dyspeptic	71	14.632	16.423	2.288	124.86
		Control	66	13.615	6.063	6.200	40.802
		Diff (1-2)	_	1.017	12.552	_	_
	Rice	Dyspeptic	71	27.793	23.531	2.275	130.23
		Control	66	21.551	16.950	3.350	92.642
		Diff (1-2)	_	6.241	20.626	_	_
	Rye	Dyspeptic	71	8.221	7.976	0.597	44.874
		Control	66	5.237	3.633	0.100	22.824
		Diff (1-2)	_	2.984	6.272	_	_
	Safflower	Dyspeptic	71	9.937	11.916	0.796	84.905
		Control	66	8.776	8.189	1.722	48.833
		Diff (1-2)	_	1.161	10.291	_	_
	Salmon	Dyspeptic	71	8.717	11.222	0.616	87.396
		Control	66	9.377	7.261	2.862	56.530
		Diff (1-2)	_	-0.660	9.523	_	_
	Sardine	Dyspeptic	71	37.499	20.190	1.020	96.528
		Control	66	37.084	16.695	7.190	88.964
		Diff (1-2)	_	0.415	18.589	_	_
	Scallop	Dyspeptic	71	61.538	41.346	2.077	191.69
		Control	66	64.291	29.551	18.605	148.58
		Diff (1-2)	_	-2.753	36.151	_	_
	Sesame	Dyspeptic	71	69.657	92.009	0.791	400.00
		Control	66	80.704	93.902	5.984	400.00
		Diff (1-2)	_	-11.047	92.926	_	_
	Shrimp	Dyspeptic	71	16.958	14.950	1.691	83.493
		Control	66	33.150	27.875	6.607	113.66
		Diff (1-2)	_	-16.192	22.136	_	_
	Sole	Dyspeptic	71	4.602	2.555	0.517	14.482
		Control	66	6.440	6.960	0.100	54.883
		Diff (1-2)	_	-1.838	5.168	_	_
	Soybean	Dyspeptic	71	17.300	14.032	1.384	94.185
		Control	66	15.294	9.373	2.481	49.071
		Diff (1-2)	_	2.006	12.016	_	_
	Spinach	Dyspeptic	71	18.224	13.972	1.978	89.498
		Control	66	20.485	13.172	6.051	66.626
		Diff (1-2)	_	-2.261	13.593	_	_

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
	Squashes	Dyspeptic	71	14.792	10.503	3.363	59.327
		Control	66	13.415	11.597	1.842	74.279
		Diff (1-2)	_	1.377	11.043	_	_
	Strawberry	Dyspeptic	71	5.541	6.234	0.125	33.622
		Control	66	5.563	5.305	0.100	35.745
		Diff (1-2)	_	-0.021	5.805	_	_
	String_Bean	Dyspeptic	71	47.793	30.409	3.659	167.25
		Control	66	41.957	22.678	9.539	125.69
		Diff (1-2)	_	5.836	26.965	_	_
	Sunflower_Sd	Dyspeptic	71	11.594	9.287	1.492	44.708
		Control	66	9.948	6.094	2.632	33.347
		Diff (1-2)	_	1.645	7.912	_	_
	Sweet_Pot_	Dyspeptic	71	8.782	7.084	1.193	38.030
		Control	66	8.592	4.479	0.395	25.009
		Diff (1-2)	_	0.189	5.973	_	_
	Swiss_Ch_	Dyspeptic	71	78.308	114.138	0.989	400.00
		Control	66	39.219	73.725	0.100	400.00
		Diff (1-2)	_	39.088	96.809	_	_
	Tea	Dyspeptic	71	32.374	18.485	5.143	120.55
		Control	66	29.771	12.014	11.634	64.535
		Diff (1-2)	_	2.603	15.706	_	_
	Tobacco	Dyspeptic	71	52.420	46.360	7.518	292.18
		Control	66	33.566	16.789	7.809	82.097
		Diff (1-2)	_	18.855	35.357	_	_
	Tomato	Dyspeptic	71	11.814	14.291	0.696	98.064
		Control	66	9.066	7.694	0.100	42.078
		Diff (1-2)	_	2.748	11.593	_	_
	Trout	Dyspeptic	71	12.771	16.216	1.275	133.51
		Control	66	16.138	10.667	5.596	76.221
		Diff (1-2)	_	-3.366	13.825	_	_
	Tuna	Dyspeptic	71	16.600	18.989	2.089	101.29
		Control	66	18.092	12.707	3.873	64.090
		Diff (1-2)	_	-1.492	16.270	_	_
	Turkey	Dyspeptic	71	14.648	16.650	2.755	112.78
		Control	66	14.461	6.976	4.094	32.151
		Diff (1-2)	_	0.186	12.930	_	_
	Walnut_Blk	Dyspeptic	71	33.355	34.630	3.561	232.09

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
		Control	66	25.386	17.254	6.943	117.46
		Diff (1-2)	_	7.969	27.661	_	_
	Wheat	Dyspeptic	71	32.468	47.786	1.339	215.09
		Control	66	18.402	29.364	0.790	209.95
		Diff (1-2)	_	14.066	39.990	_	_
	Yeast_Baker	Dyspeptic	71	14.361	19.137	0.796	83.616
		Control	66	5.545	3.349	0.526	18.811
		Diff (1-2)	_	8.815	13.975	_	_
	Yeast_Brewer	Dyspeptic	71	33.059	44.903	0.995	192.30
		Control	66	10.847	7.818	0.100	43.887
		Diff (1-2)	_	22.213	32.786	_	_
	Yogurt	Dyspeptic	71	31.407	47.964	2.288	341.69
		Control	66	22.930	30.973	0.100	215.73
		Diff (1-2)	_	8.478	40.679	_	_
MALE	Almond	Dyspeptic	69	5.486	5.761	0.100	30.384
		Control	97	4.049	2.231	0.100	12.591
		Diff (1-2)	_	1.437	4.083	_	_
	Amer__Cheese	Dyspeptic	69	49.696	103.376	0.100	400.00
		Control	97	22.619	34.069	0.468	197.38
		Diff (1-2)	_	27.077	71.487	_	_
	Apple	Dyspeptic	69	4.460	4.547	0.100	28.069
		Control	97	4.383	2.900	0.100	13.795
		Diff (1-2)	_	0.078	3.674	_	_
	Avocado	Dyspeptic	69	3.210	4.016	0.100	26.220
		Control	97	2.720	2.992	0.100	28.693
		Diff (1-2)	_	0.490	3.453	_	_
	Banana	Dyspeptic	69	9.992	17.833	0.100	92.849
		Control	97	8.576	36.151	0.100	350.69
		Diff (1-2)	_	1.416	29.948	_	_
	Barley	Dyspeptic	69	27.317	21.432	5.731	142.44
		Control	97	19.214	11.923	4.612	58.865
		Diff (1-2)	_	8.103	16.543	_	_
	Beef	Dyspeptic	69	16.037	49.047	0.174	400.00
		Control	97	9.327	11.981	2.059	93.494
		Diff (1-2)	_	6.711	32.886	_	_
	Blueberry	Dyspeptic	69	4.244	3.021	0.100	20.552
		Control	97	5.393	2.868	0.100	19.410

Sex	Food	Diagnosis	N	ELISA Score Mean	SD	Min	Max
		Diff (1-2)	_	-1.149	2.933	_	_
	Broccoli	Dyspeptic	69	8.098	6.538	0.564	35.134
		Control	97	6.790	8.012	0.131	72.543
		Diff (1-2)	_	1.309	7.437	_	_
	Buck_Wheat	Dyspeptic	69	8.927	6.251	1.354	28.680
		Control	97	6.978	3.384	2.656	24.338
		Diff (1-2)	_	1.949	4.786	_	_
	Butter	Dyspeptic	69	36.958	61.387	0.843	400.00
		Control	97	17.846	20.091	1.490	131.60
		Diff (1-2)	_	19.112	42.412	_	_
	Cabbage	Dyspeptic	69	9.321	13.246	0.451	66.852
		Control	97	6.540	18.133	0.100	174.96
		Diff (1-2)	_	2.781	16.286	_	_
	Cane_Sugar	Dyspeptic	69	23.788	15.360	3.425	78.430
		Control	97	22.356	18.718	2.789	100.82
		Diff (1-2)	_	1.432	17.404	_	_
	Cantaloupe	Dyspeptic	69	7.348	7.052	0.100	45.347
		Control	97	6.052	5.569	0.468	38.706
		Diff (1-2)	_	1.297	6.227	_	_
	Carrot	Dyspeptic	69	5.702	6.691	0.100	44.561
		Control	97	4.684	3.636	0.468	28.593
		Diff (1-2)	_	1.018	5.128	_	_
	Cashew	Dyspeptic	69	10.831	14.985	0.771	98.054
		Control	97	8.362	10.271	0.100	55.749
		Diff (1-2)	_	2.469	12.444	_	_
	Cauliflower	Dyspeptic	69	6.497	8.383	0.100	56.587
		Control	97	4.385	4.396	0.100	36.593
		Diff (1-2)	_	2.111	6.360	_	_
	Celery	Dyspeptic	69	9.947	6.957	0.285	39.308
		Control	97	8.930	4.985	2.394	26.982
		Diff (1-2)	_	1.018	5.883	_	_
	Cheddar_Ch_	Dyspeptic	69	60.561	118.961	0.100	400.00
		Control	97	28.479	49.022	1.169	298.91
		Diff (1-2)	_	32.082	85.291	_	_
	Chicken	Dyspeptic	69	23.643	27.818	3.271	192.78
		Control	97	17.778	11.456	5.137	69.503
		Diff (1-2)	_	5.865	19.942	_	_

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
	Chili_Pepper	Dyspeptic	69	7.347	5.323	1.371	28.301
		Control	97	7.802	5.945	1.591	31.070
		Diff (1-2)	_	-0.454	5.695	_	_
	Chocolate	Dyspeptic	69	20.817	17.801	4.221	123.11
		Control	97	16.536	11.276	1.726	63.673
		Diff (1-2)	_	4.280	14.347	_	_
	Cinnamon	Dyspeptic	69	49.454	39.614	2.015	199.16
		Control	97	35.928	28.520	3.136	146.95
		Diff (1-2)	_	13.526	33.568	_	_
	Clam	Dyspeptic	69	44.661	28.761	4.809	154.43
		Control	97	38.293	21.598	6.370	103.47
		Diff (1-2)	_	6.368	24.820	_	_
	Codfish	Dyspeptic	69	21.984	17.791	3.713	114.33
		Control	97	22.538	29.644	4.176	269.16
		Diff (1-2)	_	-0.554	25.409	_	_
	Coffee	Dyspeptic	69	20.100	29.054	2.123	171.42
		Control	97	20.037	24.002	2.705	192.24
		Diff (1-2)	_	0.064	26.215	_	_
	Cola_Nut	Dyspeptic	69	41.927	23.517	6.217	116.84
		Control	97	32.919	20.025	3.851	112.10
		Diff (1-2)	_	9.008	21.542	_	_
	Corn	Dyspeptic	69	13.772	16.658	0.571	94.627
		Control	97	10.126	15.048	1.520	117.90
		Diff (1-2)	_	3.647	15.736	_	_
	Cottage_Ch_	Dyspeptic	69	111.185	133.261	0.100	400.00
		Control	97	74.814	101.386	1.446	400.00
		Diff (1-2)	_	36.372	115.673	_	_
	Cow_Milk	Dyspeptic	69	108.116	129.724	0.100	400.00
		Control	97	68.606	94.032	1.343	400.00
		Diff (1-2)	_	39.510	110.243	_	_
	Crab	Dyspeptic	69	26.790	48.613	1.643	400.00
		Control	97	24.550	29.311	3.108	252.41
		Diff (1-2)	_	2.240	38.507	_	_
	Cucumber	Dyspeptic	69	11.071	12.416	0.100	57.699
		Control	97	8.320	9.298	0.234	69.188
		Diff (1-2)	_	2.751	10.702	_	_
	Egg	Dyspeptic	69	59.326	97.416	0.100	400.00

Sex	Food	Diagnosis	N	ELISA Score Mean	SD	Min	Max
		Control	97	44.335	66.828	0.100	400.00
		Diff (1-2)	_	14.992	80.926	_	_
	Eggplant	Dyspeptic	69	5.655	5.975	0.100	31.426
		Control	97	5.856	10.455	0.100	92.376
		Diff (1-2)	_	-0.201	8.876	_	_
	Garlic	Dyspeptic	69	11.701	9.010	2.216	47.092
		Control	97	13.476	12.122	3.097	70.591
		Diff (1-2)	_	-1.774	10.940	_	_
	Goat_Milk	Dyspeptic	69	26.110	58.010	0.100	400.00
		Control	97	17.999	36.202	0.100	275.19
		Diff (1-2)	_	8.111	46.503	_	_
	Grape	Dyspeptic	69	17.358	8.648	7.156	58.516
		Control	97	23.308	7.422	11.900	41.654
		Diff (1-2)	_	-5.950	7.954	_	_
	Grapefruit	Dyspeptic	69	4.092	5.501	0.100	27.722
		Control	97	3.049	2.306	0.100	14.648
		Diff (1-2)	_	1.043	3.957	_	_
	Green_Pea	Dyspeptic	69	12.842	12.531	1.642	64.004
		Control	97	9.229	11.366	0.100	71.765
		Diff (1-2)	_	3.612	11.863	_	_
	Green_Pepper	Dyspeptic	69	4.999	6.104	0.100	37.221
		Control	97	3.972	2.664	0.100	15.744
		Diff (1-2)	_	1.027	4.428	_	_
	Halibut	Dyspeptic	69	12.562	19.913	2.619	157.86
		Control	97	12.657	15.451	0.818	142.09
		Diff (1-2)	_	-0.095	17.440	_	_
	Honey	Dyspeptic	69	12.900	13.717	1.919	99.306
		Control	97	11.082	6.215	2.434	31.202
		Diff (1-2)	_	1.818	10.032	_	_
	Lemon	Dyspeptic	69	3.117	5.023	0.100	30.675
		Control	97	2.310	1.436	0.100	8.383
		Diff (1-2)	_	0.807	3.416	_	_
	Lettuce	Dyspeptic	69	10.482	7.166	1.216	37.939
		Control	97	11.271	8.295	2.871	52.209
		Diff (1-2)	_	-0.789	7.846	_	_
	Lima_Bean	Dyspeptic	69	7.488	6.768	1.233	35.171
		Control	97	5.994	5.650	0.100	37.640

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
		Diff (1-2)	_	1.495	6.139	_	_
	Lobster	Dyspeptic	69	18.437	34.093	1.890	283.99
		Control	97	15.678	11.555	0.468	61.064
		Diff (1-2)	_	2.760	23.667	_	_
	Malt	Dyspeptic	69	26.377	15.654	8.000	77.178
		Control	97	21.137	12.373	3.182	58.638
		Diff (1-2)	_	5.240	13.829	_	_
	Millet	Dyspeptic	69	4.182	5.115	0.100	36.465
		Control	97	4.006	6.783	0.100	67.831
		Diff (1-2)	_	0.176	6.146	_	_
	Mushroom	Dyspeptic	69	10.243	10.582	0.226	58.607
		Control	97	12.883	12.397	1.350	59.949
		Diff (1-2)	_	-2.639	11.679	_	_
	Mustard	Dyspeptic	69	12.907	15.309	2.120	92.807
		Control	97	9.168	5.413	1.044	28.538
		Diff (1-2)	_	3.739	10.692	_	_
	Oat	Dyspeptic	69	27.950	49.019	1.806	372.55
		Control	97	20.964	22.946	1.461	107.25
		Diff (1-2)	_	6.986	36.118	_	_
	Olive	Dyspeptic	69	22.947	15.533	4.030	80.545
		Control	97	24.794	22.708	5.137	160.63
		Diff (1-2)	_	-1.848	20.047	_	_
	Onion	Dyspeptic	69	14.318	17.212	0.677	100.13
		Control	97	11.600	17.551	1.175	158.57
		Diff (1-2)	_	2.718	17.411	_	_
	Orange	Dyspeptic	69	29.192	44.867	2.120	334.31
		Control	97	17.767	16.361	2.146	79.419
		Diff (1-2)	_	11.425	31.486	_	_
	Oyster	Dyspeptic	69	51.074	66.879	6.283	400.00
		Control	97	43.016	35.689	5.069	216.58
		Diff (1-2)	_	8.058	50.992	_	_
	Parsley	Dyspeptic	69	5.017	9.512	0.100	61.531
		Control	97	4.867	7.352	0.100	58.674
		Diff (1-2)	_	0.150	8.316	_	_
	Peach	Dyspeptic	69	7.240	6.466	0.347	38.148
		Control	97	8.390	8.373	0.100	50.444
		Diff (1-2)	_	-1.150	7.640	_	_

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
	Peanut	Dyspeptic	69	6.089	7.833	0.100	38.521
		Control	97	4.241	4.514	0.855	41.070
		Diff (1-2)	_	1.848	6.113	_	_
	Pineapple	Dyspeptic	69	24.610	30.753	1.544	162.69
		Control	97	23.259	48.769	0.100	400.00
		Diff (1-2)	_	1.351	42.242	_	_
	Pinto_Bean	Dyspeptic	69	8.186	7.051	0.914	37.104
		Control	97	8.132	5.524	0.664	28.288
		Diff (1-2)	_	0.054	6.203	_	_
	Pork	Dyspeptic	69	13.632	13.813	1.890	96.139
		Control	97	13.403	10.218	1.637	57.274
		Diff (1-2)	_	0.229	11.842	_	_
	Potato	Dyspeptic	69	12.011	7.875	3.957	48.138
		Control	97	14.555	5.951	5.259	49.002
		Diff (1-2)	_	-2.544	6.815	_	_
	Rice	Dyspeptic	69	27.818	18.142	6.096	82.830
		Control	97	25.220	18.948	5.149	118.12
		Diff (1-2)	_	2.598	18.618	_	_
	Rye	Dyspeptic	69	7.403	10.057	0.100	60.534
		Control	97	4.801	2.690	0.653	15.288
		Diff (1-2)	_	2.602	6.795	_	_
	Safflower	Dyspeptic	69	11.007	10.996	2.380	62.067
		Control	97	8.672	6.177	1.958	38.914
		Diff (1-2)	_	2.335	8.513	_	_
	Salmon	Dyspeptic	69	10.435	14.322	0.100	94.443
		Control	97	10.920	13.350	0.100	125.74
		Diff (1-2)	_	-0.485	13.761	_	_
	Sardine	Dyspeptic	69	41.806	18.976	9.715	112.76
		Control	97	37.035	15.979	7.037	90.406
		Diff (1-2)	_	4.771	17.284	_	_
	Scallop	Dyspeptic	69	62.272	35.442	14.394	203.68
		Control	97	60.721	32.618	8.942	167.75
		Diff (1-2)	_	1.551	33.818	_	_
	Sesame	Dyspeptic	69	52.608	86.410	2.794	400.00
		Control	97	60.406	79.861	2.115	400.00
		Diff (1-2)	_	-7.798	82.639	_	_
	Shrimp	Dyspeptic	69	34.935	59.099	4.384	400.00

Sex	Food	Diagnosis	N	ELISA Score Mean	SD	Min	Max
		Control	97	34.490	42.689	2.663	342.67
		Diff (1-2)	_	0.445	50.149	_	_
	Sole	Dyspeptic	69	5.187	4.128	0.100	27.277
		Control	97	4.912	2.238	0.100	14.303
		Diff (1-2)	_	0.275	3.162	_	_
	Soybean	Dyspeptic	69	18.194	15.588	1.688	92.500
		Control	97	15.880	9.273	4.912	71.264
		Diff (1-2)	_	2.314	12.292	_	_
	Spinach	Dyspeptic	69	18.272	12.760	4.221	83.203
		Control	97	14.656	7.304	3.054	39.867
		Diff (1-2)	_	3.616	9.937	_	_
	Squashes	Dyspeptic	69	13.520	8.566	3.091	44.882
		Control	97	12.688	7.539	1.637	49.775
		Diff (1-2)	_	0.832	7.981	_	_
	Strawberry	Dyspeptic	69	4.642	5.569	0.100	31.818
		Control	97	4.767	4.446	0.100	30.664
		Diff (1-2)	_	-0.125	4.943	_	_
	String_Bean	Dyspeptic	69	47.778	28.291	11.904	164.31
		Control	97	40.720	22.088	5.609	141.76
		Diff (1-2)	_	7.058	24.849	_	_
	Sunflower_Sd	Dyspeptic	69	11.942	7.847	3.060	40.585
		Control	97	9.071	5.842	2.523	46.948
		Diff (1-2)	_	2.871	6.746	_	_
	Sweet_Pot_	Dyspeptic	69	14.463	47.586	0.100	400.00
		Control	97	8.456	4.878	0.100	30.052
		Diff (1-2)	_	6.007	30.868	_	_
	Swiss_Ch_	Dyspeptic	69	71.236	124.635	0.100	400.00
		Control	97	43.413	79.791	0.100	400.00
		Diff (1-2)	_	27.822	100.835	_	_
	Tea	Dyspeptic	69	33.600	17.444	7.761	90.992
		Control	97	31.353	13.716	8.890	70.271
		Diff (1-2)	_	2.247	15.372	_	_
	Tobacco	Dyspeptic	69	45.768	35.930	8.165	214.22
		Control	97	39.354	26.787	6.106	134.30
		Diff (1-2)	_	6.414	30.908	_	_
	Tomato	Dyspeptic	69	10.005	8.311	1.525	44.649
		Control	97	9.088	7.957	0.100	48.338

				ELISA Score			
Sex	*Food*	*Diagnosis*	*N*	*Mean*	*SD*	*Min*	*Max*
		Diff (1-2)	_	0.917	8.105	_	_
	Trout	Dyspeptic	69	14.974	17.355	0.100	117.87
		Control	97	16.891	15.673	0.100	144.46
		Diff (1-2)	_	-1.917	16.391	_	_
	Tuna	Dyspeptic	69	19.870	48.628	0.100	400.00
		Control	97	18.392	16.755	3.156	110.69
		Diff (1-2)	_	1.478	33.835	_	_
	Turkey	Dyspeptic	69	17.488	23.138	2.638	158.91
		Control	97	14.840	10.829	2.789	69.572
		Diff (1-2)	_	2.648	17.048	_	_
	Walnut_Blk	Dyspeptic	69	33.537	25.903	7.706	136.74
		Control	97	25.520	14.492	4.249	71.927
		Diff (1-2)	_	8.016	20.029	_	_
	Wheat	Dyspeptic	69	20.014	25.856	2.743	155.71
		Control	97	14.494	12.413	2.741	90.037
		Diff (1-2)	_	5.520	19.168	_	_
	Yeast_Baker	Dyspeptic	69	15.021	45.044	0.844	372.96
		Control	97	9.617	17.250	1.305	116.43
		Diff (1-2)	_	5.404	31.867	_	_
	Yeast_Brewer	Dyspeptic	69	28.223	52.235	1.813	400.00
		Control	97	22.646	47.630	1.931	308.34
		Diff (1-2)	_	5.577	49.592	_	_
	Yogurt	Dyspeptic	69	32.359	57.649	0.100	370.06
		Control	97	19.210	20.751	0.234	120.51
		Diff (1-2)	_	13.149	40.374	_	_

Table 3

Upper Quantiles of ELISA Signal Scores among Control Subjects as Candidates for Test Cutpoints in Determining "Positive" or "Negative"

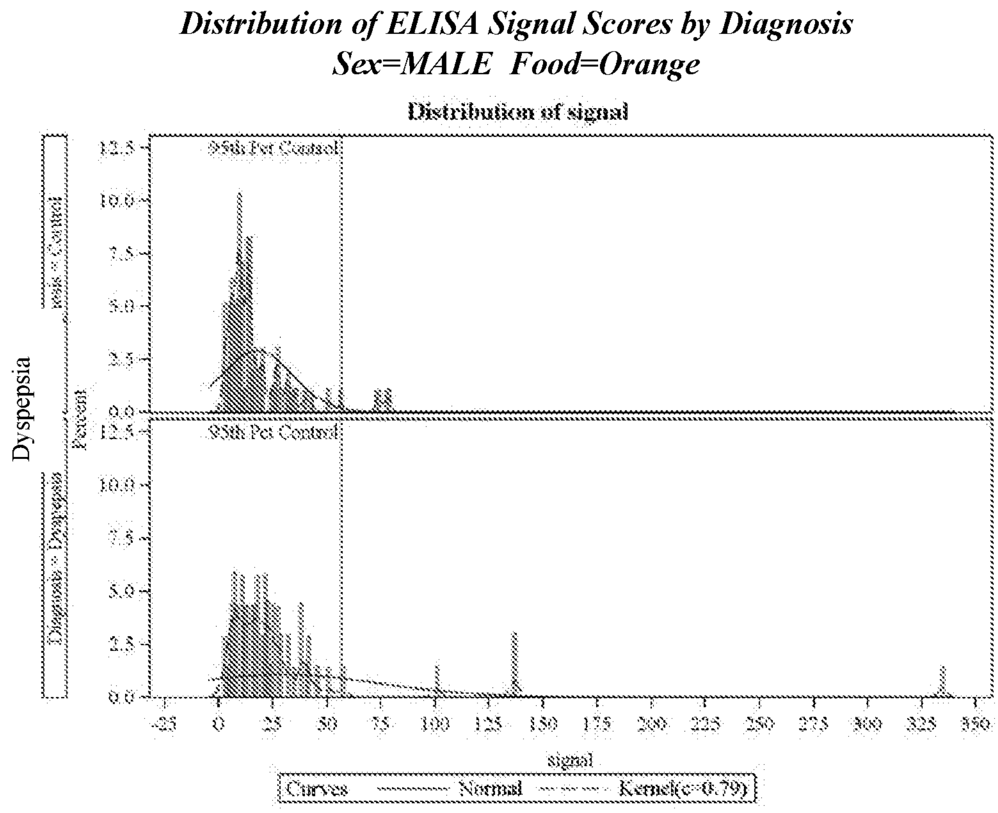
Top 37 Foods Ranked by Descending order of Discriminatory Ability using Permutation Test

			Cutpoint	
Food Ranking	*Food*	*Sex*	*90th percentile*	*95th percentile*
1	Orange	FEMALE	33.512	40.743
		MALE	37.078	56.523
2	Barley	FEMALE	34.906	46.457
		MALE	36.291	45.984
3	Oat	FEMALE	33.102	44.062
		MALE	55.629	73.575
4	Malt	FEMALE	36.539	41.632
		MALE	39.220	45.976
5	Rye	FEMALE	8.532	12.392
		MALE	8.389	10.620
6	Almond	FEMALE	6.809	8.256
		MALE	7.234	8.758
7	Butter	FEMALE	47.614	71.601
		MALE	44.039	58.236
8	Chocolate	FEMALE	23.523	25.886
		MALE	32.693	37.787
9	Cottage_Ch_	FEMALE	200.17	289.65
		MALE	221.34	346.86
10	Cow_Milk	FEMALE	199.64	251.67
		MALE	181.95	314.67
11	Cola_Nut	FEMALE	48.158	53.395
		MALE	59.913	72.836
12	Cucumber	FEMALE	20.770	26.743
		MALE	17.763	23.972
13	Amer__Cheese	FEMALE	54.066	92.253
		MALE	56.387	95.995
14	Tobacco	FEMALE	57.785	64.466
		MALE	74.157	102.79
15	Cheddar_Ch_	FEMALE	72.699	114.36
		MALE	82.049	123.72
16	Green_Pea	FEMALE	20.827	23.696
		MALE	19.763	32.455

Food Ranking	Food	Sex	Cutpoint 90th percentile	95th percentile
17	Walnut_Blk	FEMALE	45.337	56.993
		MALE	45.291	56.499
18	Swiss_Ch_	FEMALE	102.90	197.44
		MALE	112.51	220.57
19	Wheat	FEMALE	30.788	59.828
		MALE	27.190	37.936
20	Cane_Sugar	FEMALE	29.649	35.866
		MALE	45.804	65.714
21	Sunflower_Sd	FEMALE	16.510	22.655
		MALE	14.291	18.519
22	Mustard	FEMALE	17.495	19.435
		MALE	16.185	20.880
23	Yeast_Brewer	FEMALE	20.385	26.245
		MALE	40.306	97.649
24	Yeast_Baker	FEMALE	9.287	12.329
		MALE	15.004	36.584
25	Cinnamon	FEMALE	68.275	77.302
		MALE	68.900	95.001
26	Cauliflower	FEMALE	11.593	17.830
		MALE	7.955	11.116
27	Yogurt	FEMALE	45.340	66.890
		MALE	43.224	65.857
28	Grapefruit	FEMALE	6.227	7.689
		MALE	5.303	7.667
29	Cantaloupe	FEMALE	9.612	13.588
		MALE	11.261	16.117
30	Green_Pepper	FEMALE	8.331	10.396
		MALE	7.004	9.670
31	Egg	FEMALE	147.45	286.16
		MALE	107.95	196.77
32	String_Bean	FEMALE	68.493	84.208
		MALE	65.659	83.621
33	Broccoli	FEMALE	11.838	14.936
		MALE	13.102	16.150
34	Buck_Wheat	FEMALE	14.733	18.529
		MALE	11.347	12.752

			Cutpoint	
Food Ranking	*Food*	*Sex*	*90th percentile*	*95th percentile*
35	Cabbage	FEMALE	18.268	29.164
		MALE	9.631	18.503
36	Corn	FEMALE	19.569	29.031
		MALE	19.812	29.509
37	Honey	FEMALE	16.247	17.448
		MALE	19.349	24.932

Table 4



Distribution of ELISA Signal Scores by Diagnosis
Sex=MALE Food=Orange
Distribution of signal
95th Pct Control
Dyspepsia
Percent
Diagnosis = Dyspepsia
signal
Curves Normal Kernel(c=0.79)

Figure 1A

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=MALE Food=Orange

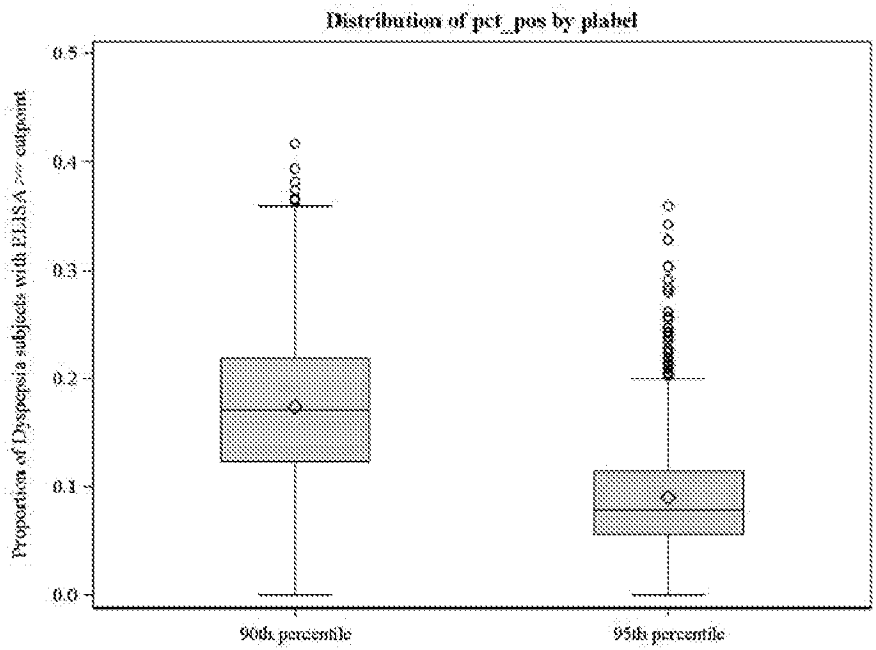


Figure 1B

Distribution of ELISA Signal Scores by Diagnosis
Sex=FEMALE Food=Orange

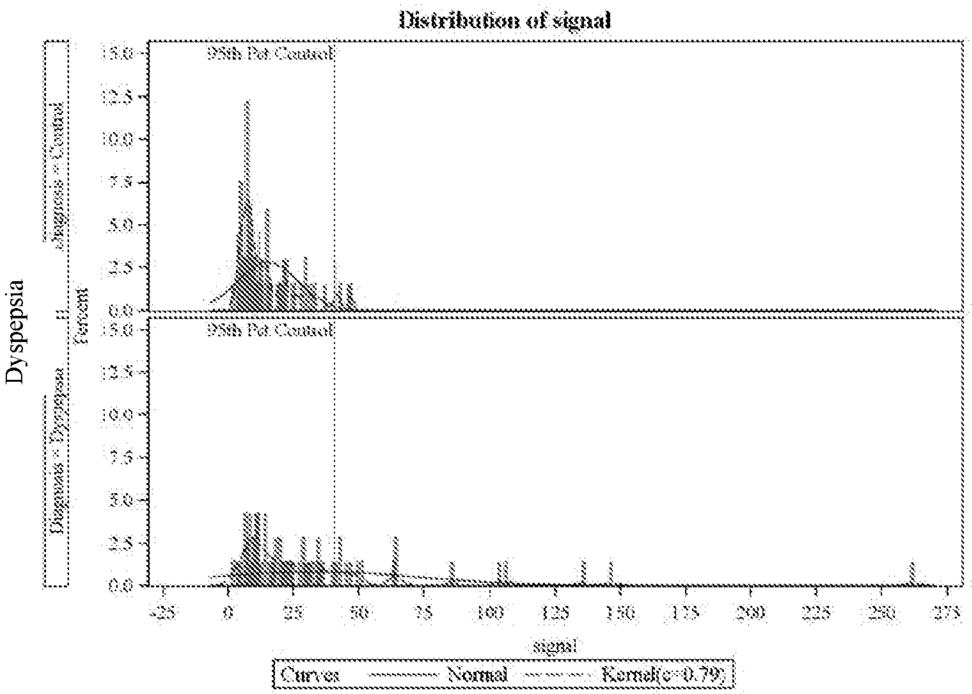


Figure 1C

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples

Sex=FEMALE Food=Orange

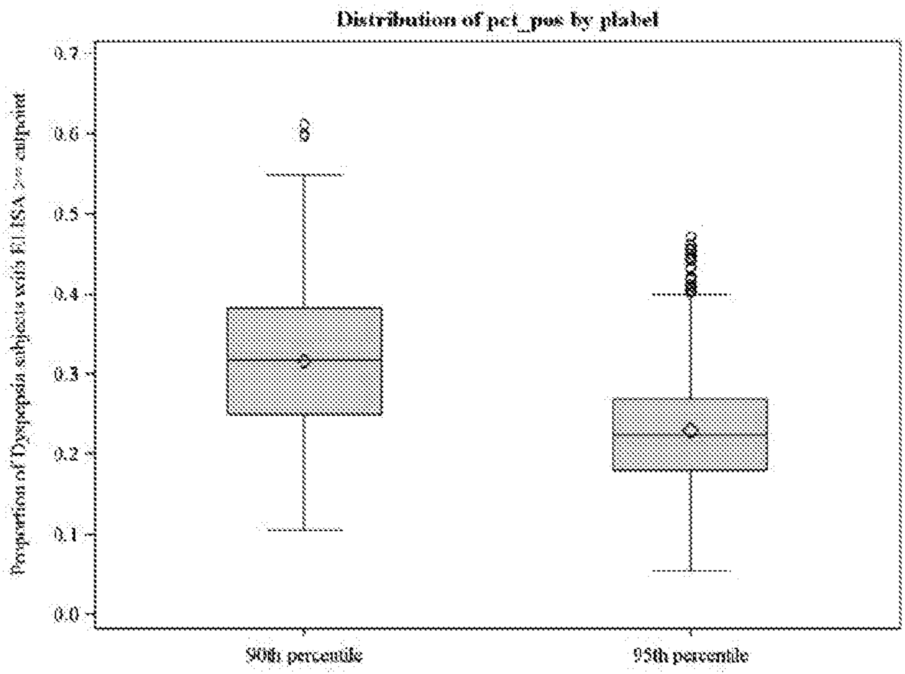


Figure 1D

Distribution of ELISA Signal Scores by Diagnosis
Sex=MALE Food=Barley

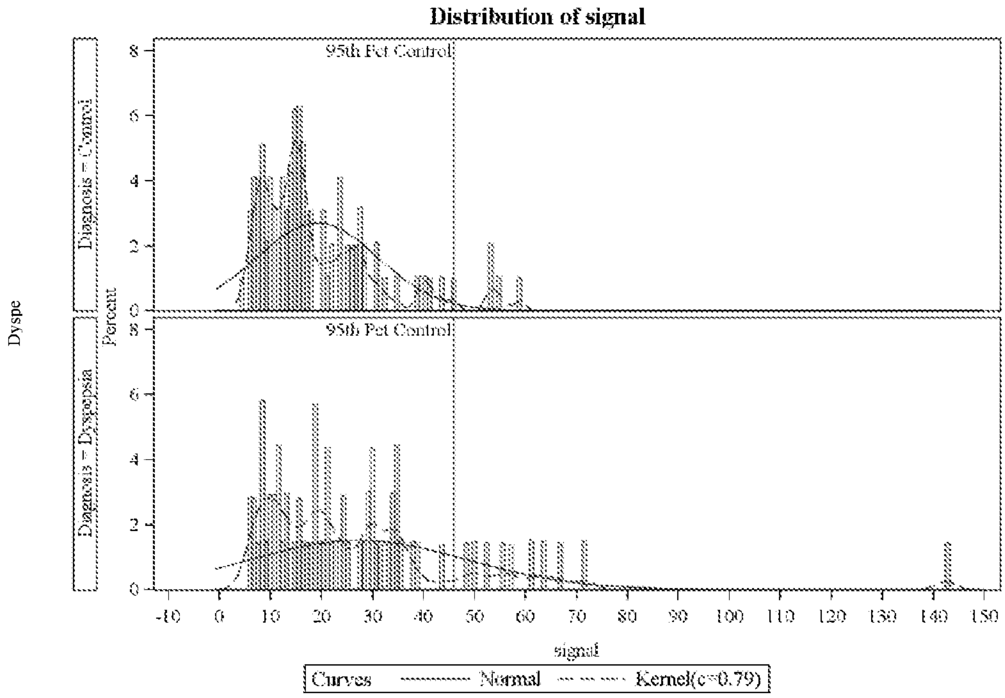


Figure 2A

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=MALE Food=Barley

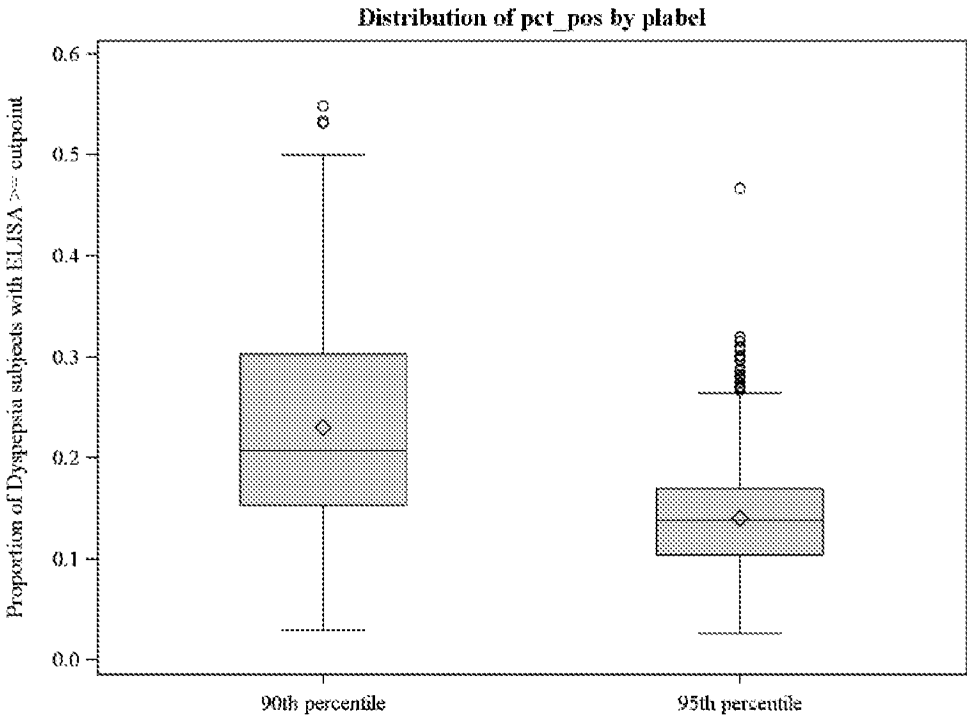


Figure 2B

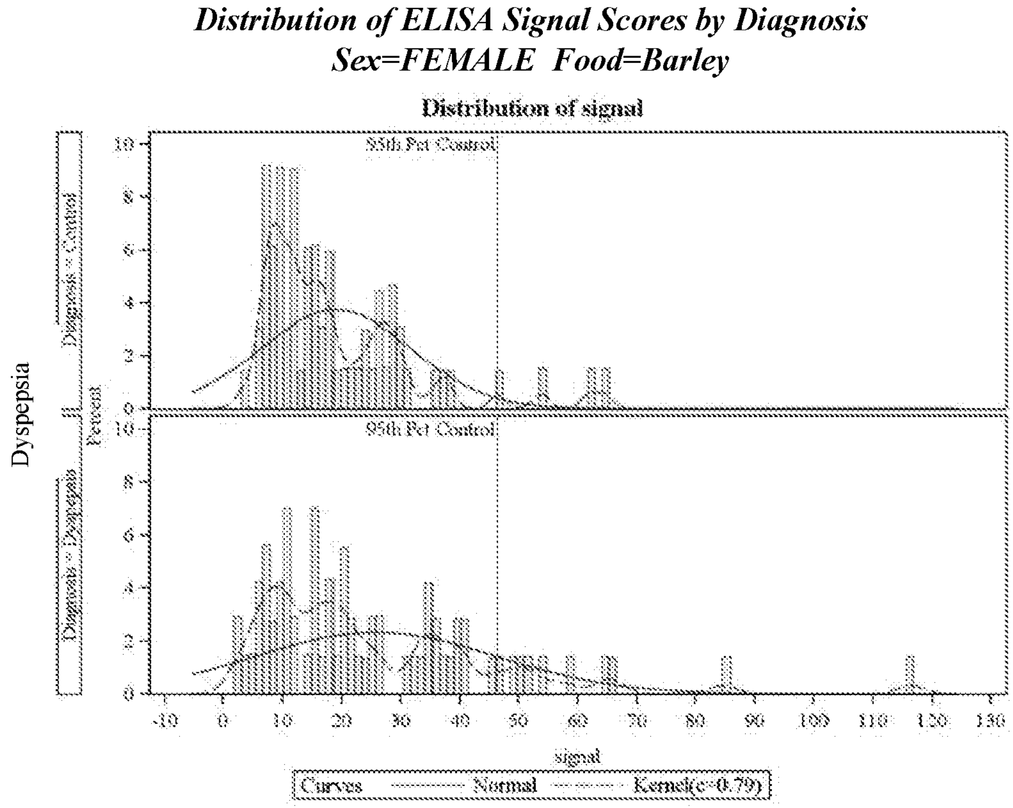

Distribution of ELISA Signal Scores by Diagnosis
Sex=FEMALE Food=Barley
Distribution of signal
95th Pct Control
Dyspepsia
Diagnosis = Control
Diagnosis = Dyspepsia
Percent
signal
Curves Normal Kernel(c=0.79)

Figure 2C

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=FEMALE Food=Barley

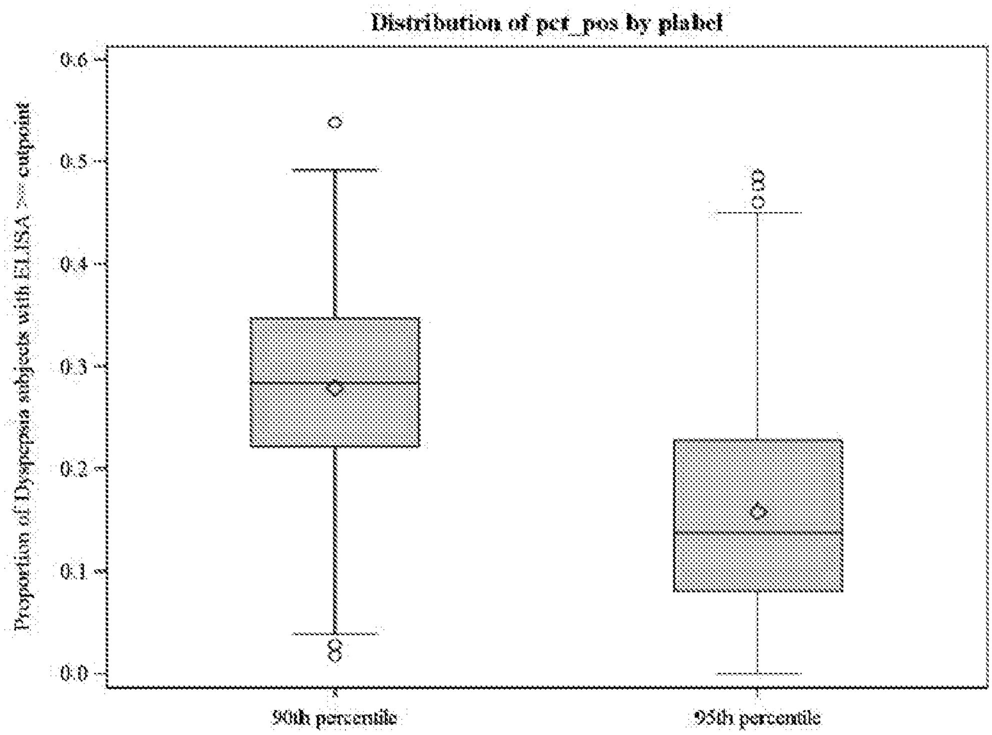


Figure 2D

Distribution of ELISA Signal Scores by Diagnosis
Sex=MALE Food=Oat

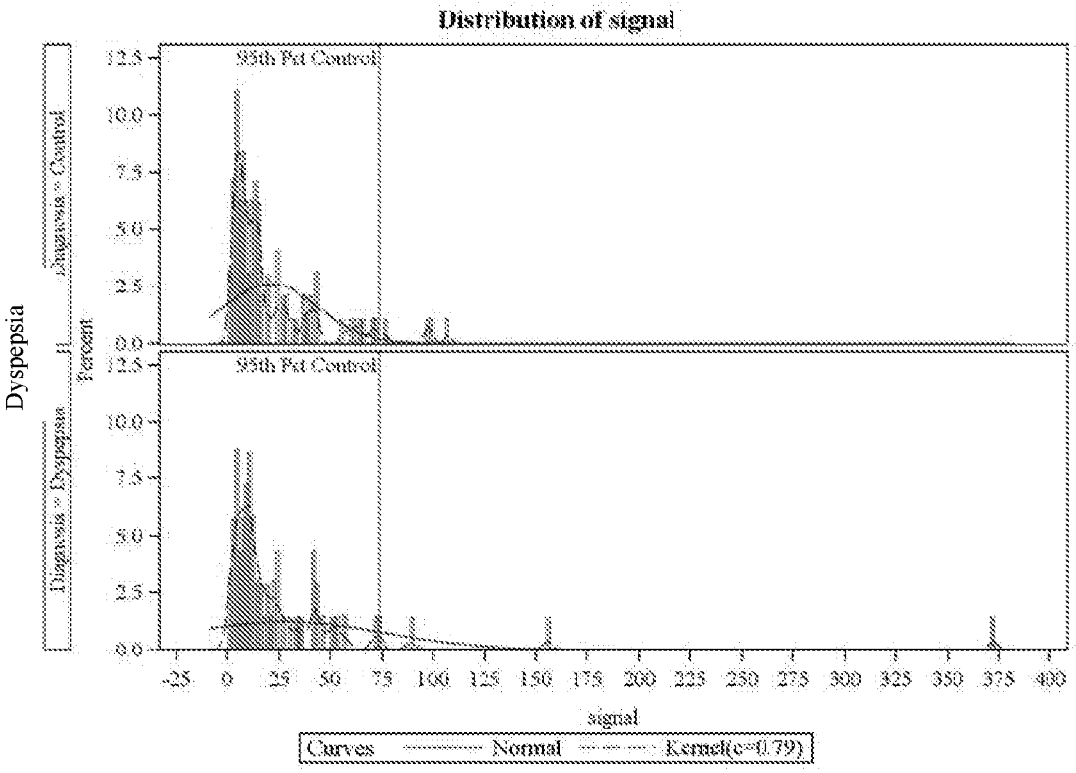


Figure 3A

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=MALE Food=Oat

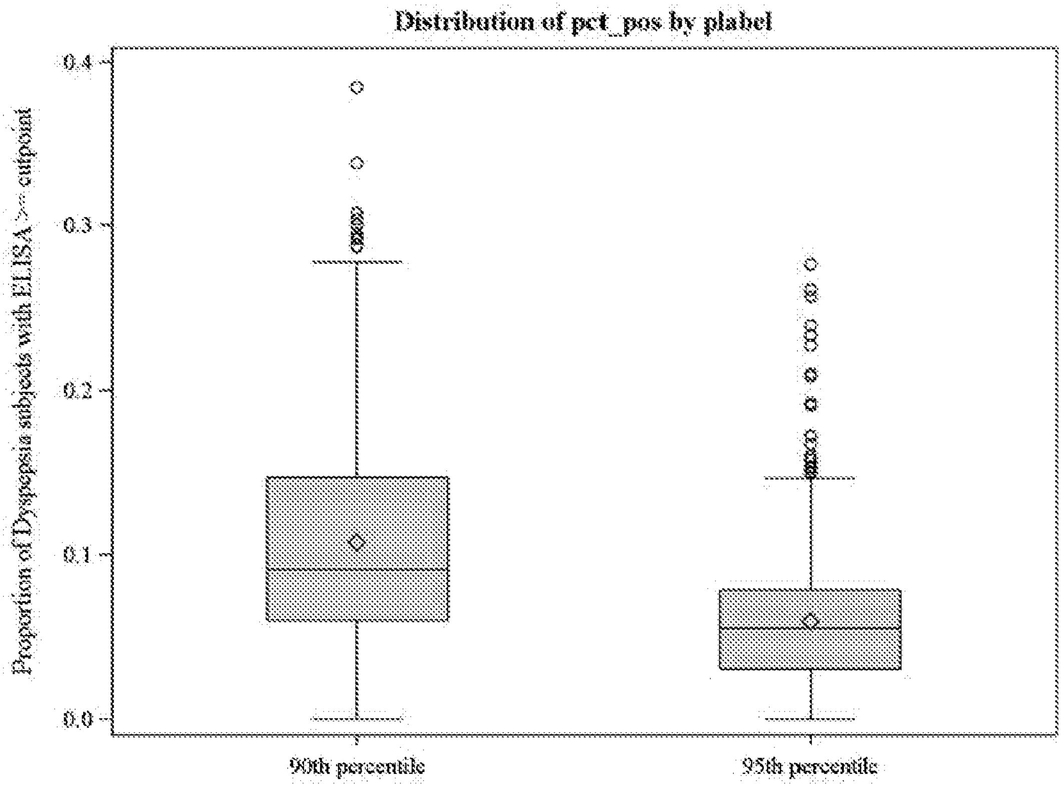


Figure 3B

Distribution of ELISA Signal Scores by Diagnosis
Sex=FEMALE Food=Oat

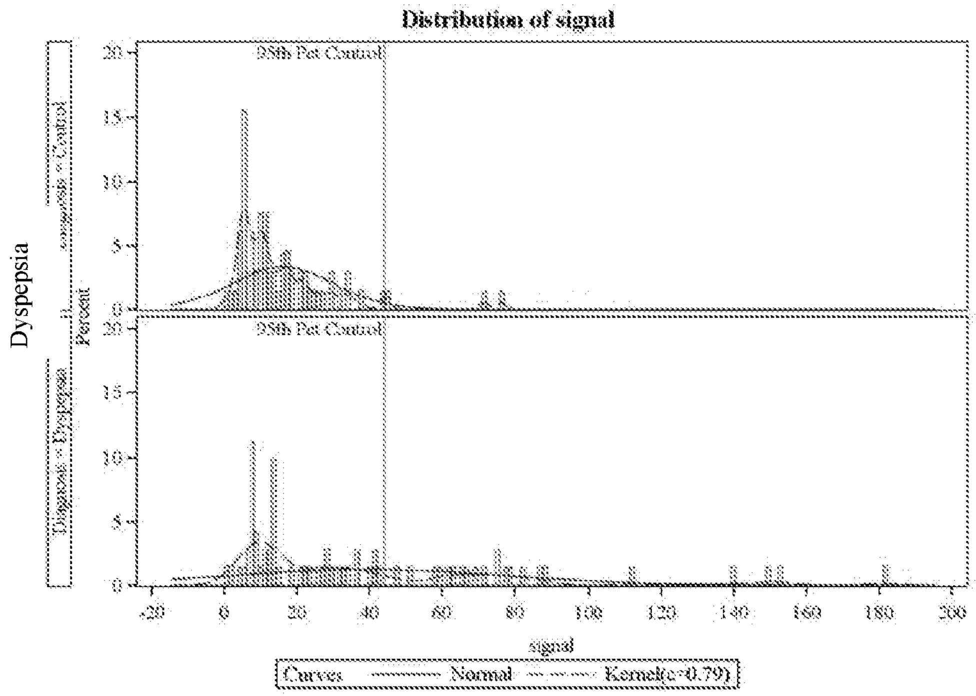


Figure 3C

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=FEMALE Food=Oat

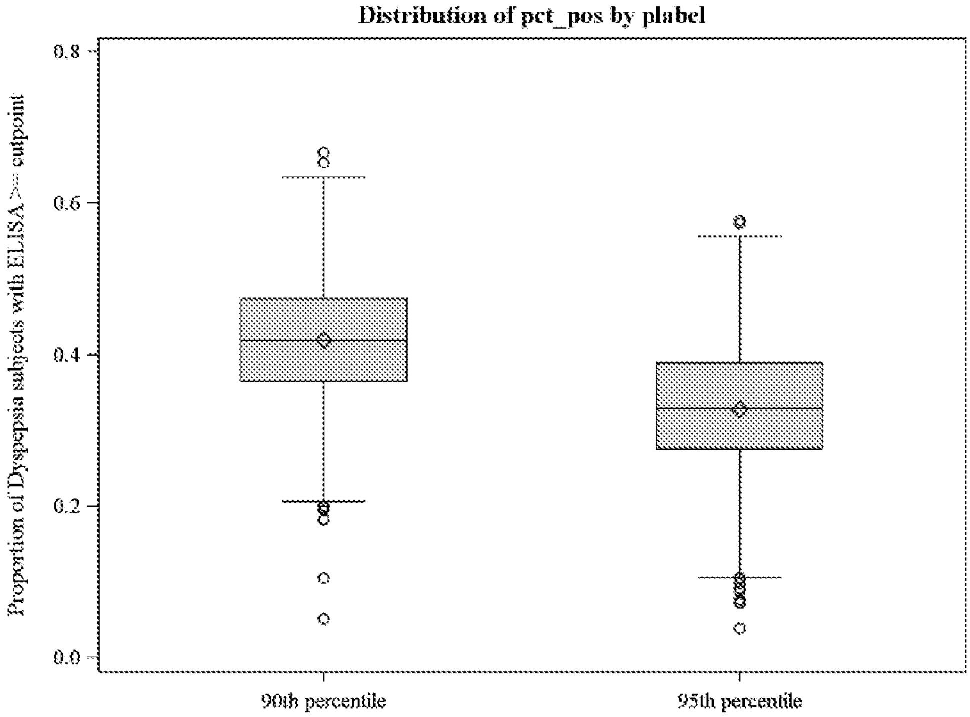


Figure 3D

Distribution of ELISA Signal Scores by Diagnosis
Sex=MALE Food=Malt

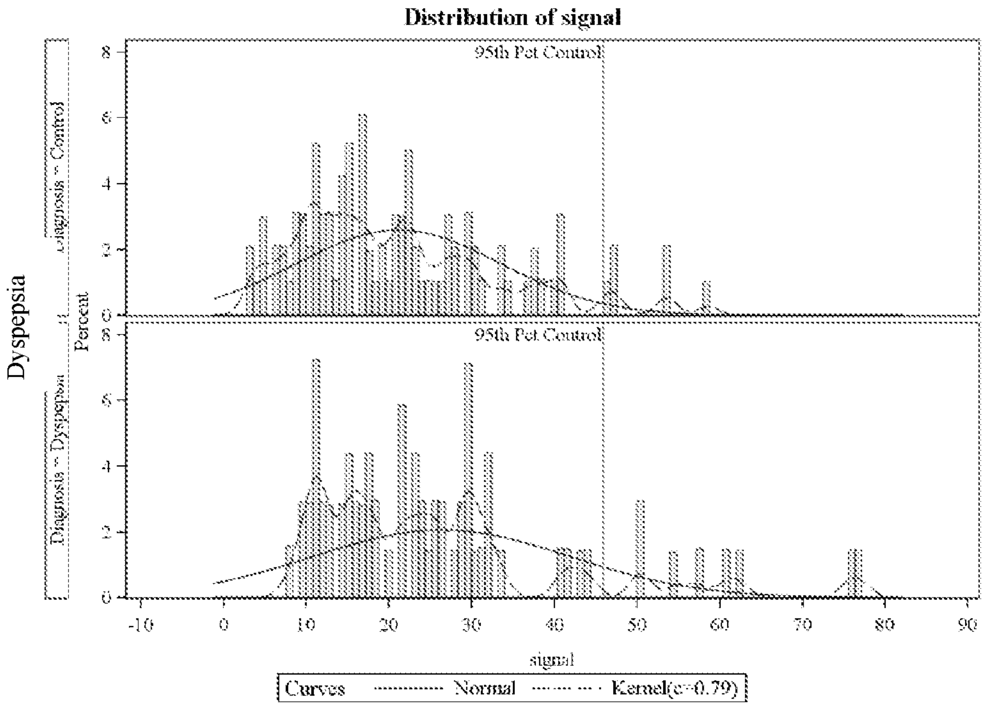


Figure 4A

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=MALE Food=Malt

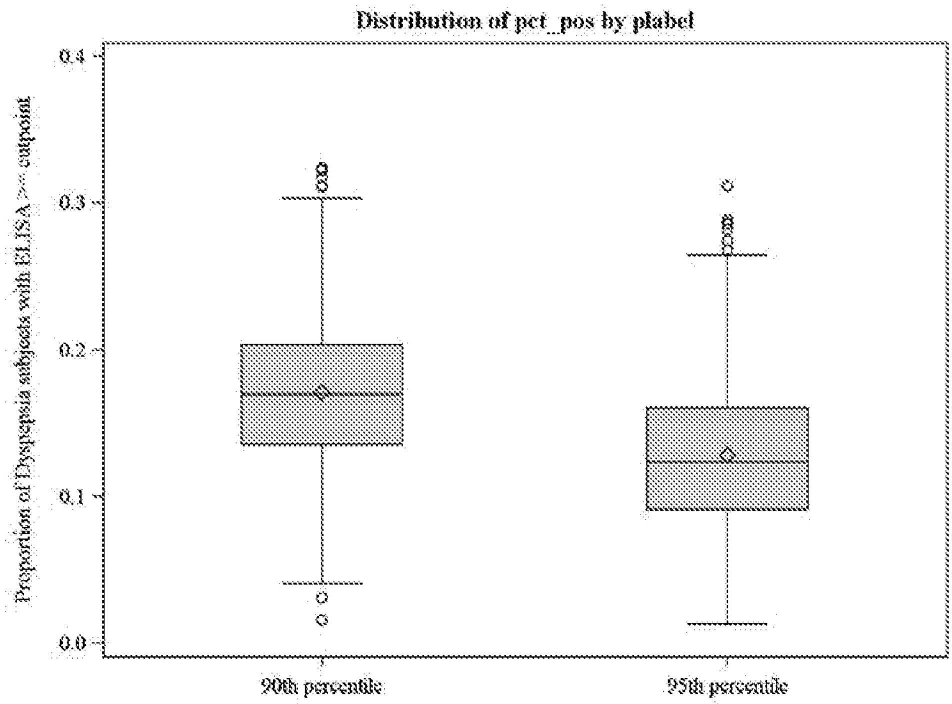


Figure 4B

Distribution of ELISA Signal Scores by Diagnosis
Sex=FEMALE Food=Malt

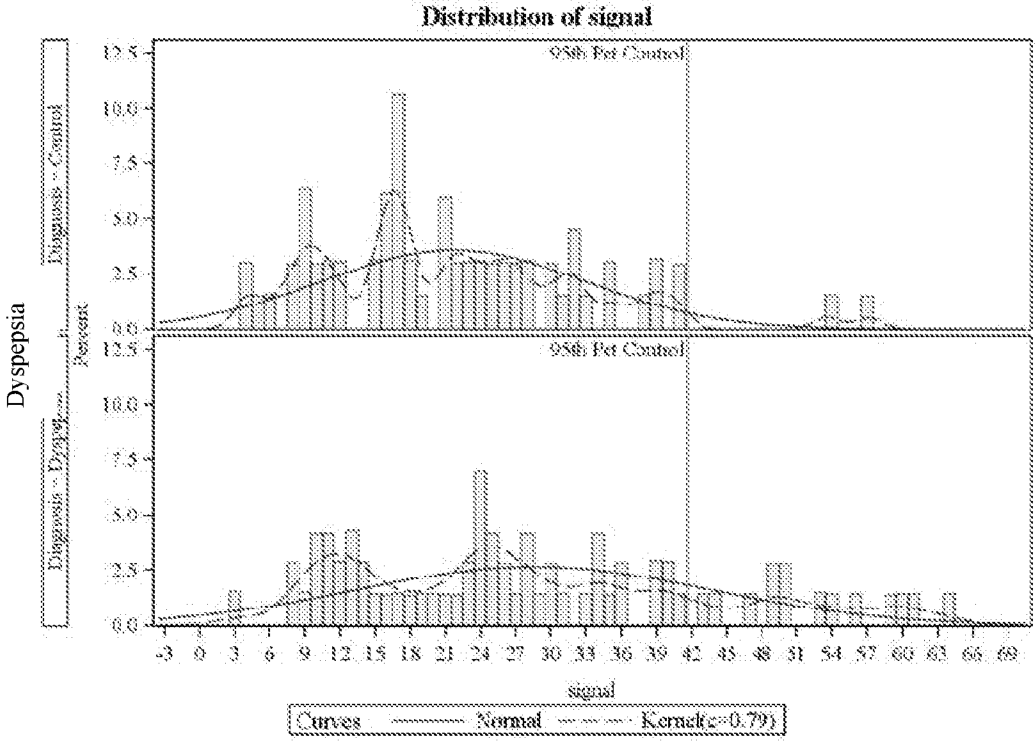


Figure 4C

Distribution of Percentage of Dyspepsia Subjects with Signals >= Control Cutpoint across 1000 Bootstrapped Samples
Sex=FEMALE Food=Malt

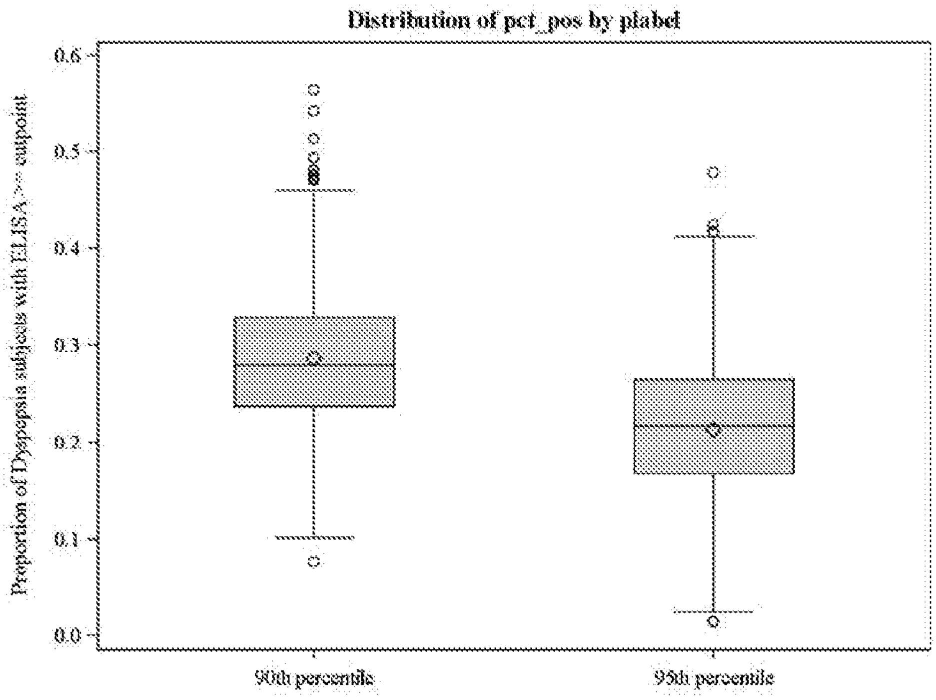


Figure 4D

Distribution of Dyspepsia Subjects by Number of Foods in which they were rated as "Positive" by Sex

90th Percentile as Cutpoint

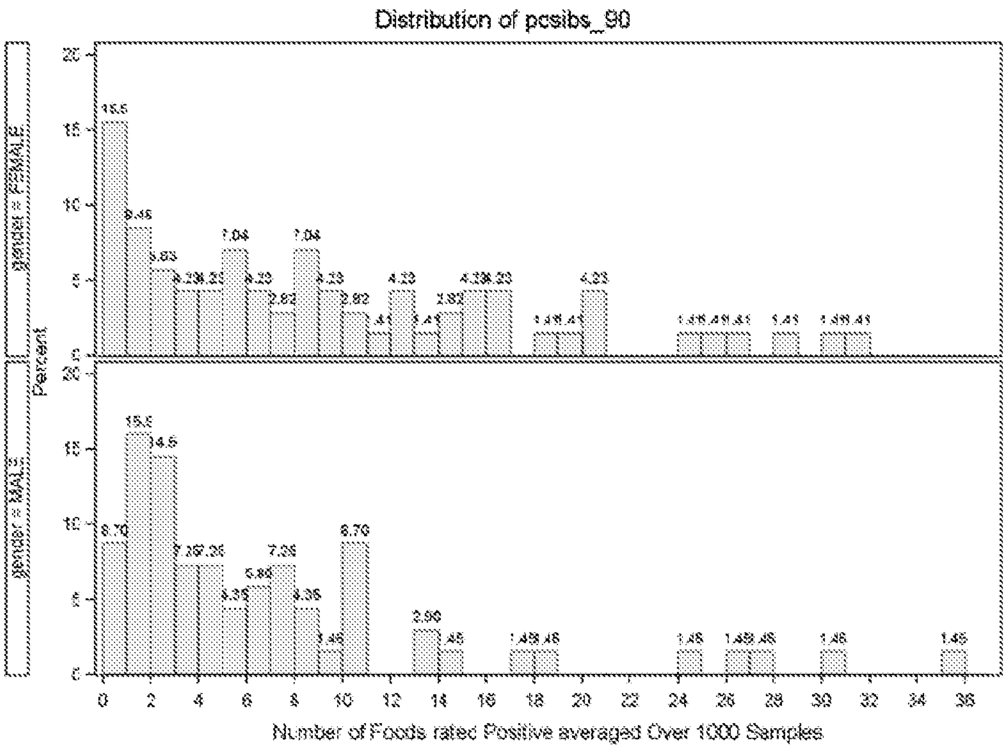


Figure 5A

Distribution of Dyspepsia Subjects by Number of Foods in which they were rated as "Positive" by Sex

95th Percentile as Cutpoint

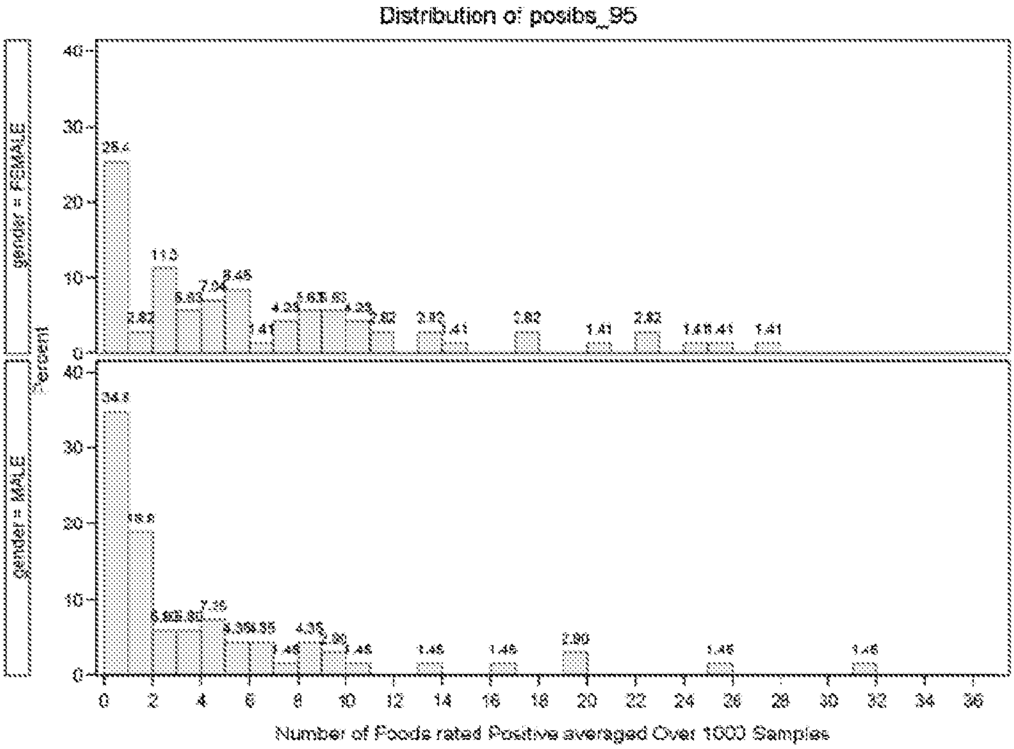


Figure 5B

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
KH16-04311	1
KH16-04370	3
KH16-04371	24
KH16-04372	0
KH16-04375	6
KH16-04376	5
KH16-04377	0
KH16-04633	6
KH16-04734	0
KH16-04736	3
KH16-04889	4
KH16-04891	1
KH16-04892	0
KH16-03340	2
KH16-03341	0
KH16-03344	2
KH16-09645	3
KH16-09649	13
KH16-09650	1
KH16-09652	1
KH16-09654	13
KH16-09655	5
KH16-09656	3
KH16-09657	18
KH16-09658	3
KH16-10150	1
KH16-10151	7
KH16-10154	3
KH16-10156	7
KH16-10157	4
KH16-10158	0
KH16-10160	2
KH16-10163	18
KH16-10165	1
KH16-11845	5
KH16-11848	2
KH16-11849	7
KH16-11850	2
KH16-11851	2
KH16-11852	12
KH16-11853	3
KH16-11854	0

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1244900	1
BRH1244901	11
BRH1244902	0
BRH1244903	0
BRH1244904	0
BRH1244905	1
BRH1244906	11
BRH1244907	0
BRH1244908	1
BRH1244909	4
BRH1244910	6
BRH1244911	0
BRH1244912	0
BRH1244913	0
BRH1244914	5
BRH1244915	0
BRH1244916	1
BRH1244917	15
BRH1244918	5
BRH1244919	0
BRH1244920	4
BRH1244921	3
BRH1244922	5
BRH1244923	0
BRH1244924	0
BRH1244925	2
BRH1244926	12
BRH1244927	2
BRH1244928	5
BRH1244929	3
BRH1244930	1
BRH1244931	0
BRH1244932	4
BRH1244933	2
BRH1244934	4
BRH1244935	11
BRH1244936	0
BRH1244937	2
BRH1244938	8
BRH1244939	1
BRH1244940	1
BRH1244941	0

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
KH16-11855	1
KH16-11856	2
KH16-11857	5
KH16-11858	7
KH16-11860	13
KH16-11862	4
KH16-11863	6
KH16-11864	2
KH16-12587	11
KH16-12590	3
KH16-12593	1
KH16-12594	0
KH16-12597	2
KH16-12599	4
KH16-12600	5
KH16-07732	14
KH16-07734	0
KH16-07735	1
KH16-07740	0
KH16-07741	2
KH16-07742	2
KH16-07744	3
KH16-07745	4
KH16-07746	5
KH16-08314	2
KH16-08323	20
KH16-08324	1
KH16-04309	2
KH16-04310	17
KH16-04373	18
KH16-04374	0
KH16-04378	0
KH16-04379	6
KH16-04380	13
KH16-04381	2
KH16-04382	0
KH16-04634	0
KH16-04635	4
KH16-04636	0
KH16-04731	7
KH16-04732	0
KH16-04733	12

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1244942	8
BRH1244943	1
BRH1244944	21
BRH1244945	0
BRH1244946	4
BRH1244947	2
BRH1244948	1
BRH1244949	2
BRH1244950	2
BRH1244951	0
BRH1244952	0
BRH1244953	0
BRH1244954	0
BRH1244955	0
BRH1244956	15
BRH1244957	0
BRH1244958	0
BRH1244959	0
BRH1244960	0
BRH1244961	1
BRH1244962	1
BRH1244963	7
BRH1244964	9
BRH1244965	0
BRH1244966	1
BRH1244967	0
BRH1244968	2
BRH1244969	2
BRH1244970	1
BRH1244971	11
BRH1244972	0
BRH1244973	2
BRH1244974	0
BRH1244975	0
BRH1244976	0
BRH1244977	0
BRH1244978	0
BRH1244979	0
BRH1244980	2
BRH1244981	1
BRH1244982	0
BRH1244983	1

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
KH16-04735	14
KH16-04890	0
KH16-03342	1
KH16-03343	14
KH16-09643	3
KH16-09644	6
KH16-09646	0
KH16-09647	2
KH16-09648	9
KH16-09651	4
KH16-09653	2
KH16-09659	9
KH16-10148	2
KH16-10149	9
KH16-10152	7
KH16-10153	0
KH16-10155	18
KH16-10159	4
KH16-10161	9
KH16-10162	6
KH16-10164	5
KH16-11846	5
KH16-11847	17
KH16-11859	0
KH16-11861	14
KH16-12588	2
KH16-12589	0
KH16-12591	15
KH16-12592	1
KH16-12595	0
KH16-12596	10
KH16-12598	1
KH16-12601	6
KH16-07730	2
KH16-07731	13
KH16-07733	5
KH16-07736	9
KH16-07737	0
KH16-07738	0
KH16-07739	19
KH16-07743	9
KH16-07747	23
KH16-07748	0

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1244984	5
BRH1244985	0
BRH1244986	0
BRH1244987	0
BRH1244988	1
BRH1244989	1
BRH1244990	0
BRH1244991	1
BRH1244992	0
BRH1244993	0
BRH1244994	1
BRH1244995	0
BRH1244996	1
BRH1244997	0
BRH1244998	5
BRH1244999	0
BRH1245000	5
BRH1245001	2
BRH1245002	2
BRH1245003	1
BRH1245004	1
BRH1245005	1
BRH1245006	0
BRH1245007	0
BRH1245008	17
BRH1245009	7
BRH1245010	1
BRH1245011	4
BRH1245012	0
BRH1245013	13
BRH1245014	0
BRH1245015	0
BRH1245016	10
BRH1245017	0
BRH1245018	0
BRH1245019	2
BRH1245020	1
BRH1245021	1
BRH1245022	11
BRH1245023	0
BRH1245024	1
BRH1245025	4
BRH1245026	1

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
KH16-08310	5
KH16-08311	3
KH16-08312	9
KH16-08313	8
KH16-08315	4
KH16-08316	6
KH16-08317	20
KH16-08318	5
KH16-08319	4
KH16-08320	12
KH16-08321	11
KH16-08322	8
KH16-08325	11

No of Observations	140
Average Number	5.5
Median Number	4

# of Patients w/ 0 Pos Results	25
% Subjects w/ 0 pos results	17.9

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1245027	5
BRH1245029	0
BRH1245030	1
BRH1245031	0
BRH1245032	0
BRH1245033	3
BRH1245034	3
BRH1245035	0
BRH1245036	12
BRH1245037	0
BRH1245038	6
BRH1245039	4
BRH1245040	1
BRH1245041	0
BRH1267320	0
BRH1267321	4
BRH1267322	7
BRH1267323	2
BRH1267327	2
BRH1267329	3
BRH1267330	0
BRH1267331	1
BRH1267333	1
BRH1267334	5
BRH1267335	4
BRH1267337	2
BRH1267338	0
BRH1267339	6
BRH1267340	5
BRH1267341	0
BRH1267342	0
BRH1267343	8
BRH1267345	0
BRH1267346	1
BRH1267347	1
BRH1267349	0

No of Observations	163
Average Number	2.5
Median Number	1

# of Patients w/ 0 Pos Results	64
% Subjects w/ 0 pos results	39.3

Table 5A

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
KH16-04311	0
KH16-04370	0
KH16-04371	19
KH16-04372	0
KH16-04375	2
KH16-04376	2
KH16-04377	0
KH16-04633	6
KH16-04734	0
KH16-04736	2
KH16-04889	1
KH16-04891	0
KH16-04892	0
KH16-03340	0
KH16-03341	0
KH16-03344	1
KH16-09645	1
KH16-09649	5
KH16-09650	1
KH16-09652	1
KH16-09654	5
KH16-09655	1
KH16-09656	0
KH16-09657	11
KH16-09658	1
KH16-10150	1
KH16-10151	7
KH16-10154	0
KH16-10156	7
KH16-10157	3
KH16-10158	0
KH16-10160	1
KH16-10163	10
KH16-10165	0
KH16-11845	4
KH16-11848	0
KH16-11849	4
KH16-11850	0
KH16-11851	1
KH16-11852	7
KH16-11853	3
KH16-11854	0

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1244900	0
BRH1244901	7
BRH1244902	0
BRH1244903	0
BRH1244904	0
BRH1244905	0
BRH1244906	5
BRH1244907	0
BRH1244908	0
BRH1244909	3
BRH1244910	2
BRH1244911	0
BRH1244912	0
BRH1244913	0
BRH1244914	5
BRH1244915	0
BRH1244916	0
BRH1244917	7
BRH1244918	0
BRH1244919	0
BRH1244920	2
BRH1244921	1
BRH1244922	1
BRH1244923	0
BRH1244924	0
BRH1244925	0
BRH1244926	11
BRH1244927	1
BRH1244928	1
BRH1244929	0
BRH1244930	1
BRH1244931	0
BRH1244932	0
BRH1244933	2
BRH1244934	2
BRH1244935	9
BRH1244936	0
BRH1244937	2
BRH1244938	3
BRH1244939	0
BRH1244940	0
BRH1244941	0

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
KH16-11855	1
KH16-11856	0
KH16-11857	3
KH16-11858	5
KH16-11860	11
KH16-11862	3
KH16-11863	6
KH16-11864	0
KH16-12587	5
KH16-12590	1
KH16-12593	0
KH16-12594	0
KH16-12597	0
KH16-12599	0
KH16-12600	1
KH16-07732	10
KH16-07734	0
KH16-07735	1
KH16-07740	0
KH16-07741	0
KH16-07742	1
KH16-07744	1
KH16-07745	0
KH16-07746	2
KH16-08314	1
KH16-08323	18
KH16-08324	1
KH16-04309	2
KH16-04310	14
KH16-04373	15
KH16-04374	0
KH16-04378	0
KH16-04379	5
KH16-04380	11
KH16-04381	1
KH16-04382	0
KH16-04634	0
KH16-04635	2
KH16-04636	0
KH16-04731	5
KH16-04732	0
KH16-04733	8

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1244942	4
BRH1244943	0
BRH1244944	6
BRH1244945	0
BRH1244946	1
BRH1244947	1
BRH1244948	0
BRH1244949	0
BRH1244950	0
BRH1244951	0
BRH1244952	0
BRH1244953	0
BRH1244954	0
BRH1244955	0
BRH1244956	13
BRH1244957	0
BRH1244958	0
BRH1244959	0
BRH1244960	0
BRH1244961	1
BRH1244962	0
BRH1244963	1
BRH1244964	4
BRH1244965	0
BRH1244966	1
BRH1244967	0
BRH1244968	0
BRH1244969	1
BRH1244970	0
BRH1244971	6
BRH1244972	0
BRH1244973	1
BRH1244974	0
BRH1244975	0
BRH1244976	0
BRH1244977	0
BRH1244978	0
BRH1244979	0
BRH1244980	2
BRH1244981	1
BRH1244982	0
BRH1244983	1

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
KH16-04735	7
KH16-04890	0
KH16-03342	1
KH16-03343	13
KH16-09643	2
KH16-09644	5
KH16-09646	0
KH16-09647	2
KH16-09648	5
KH16-09651	4
KH16-09653	1
KH16-09659	7
KH16-10148	0
KH16-10149	5
KH16-10152	4
KH16-10153	0
KH16-10155	15
KH16-10159	4
KH16-10161	4
KH16-10162	4
KH16-10164	4
KH16-11846	4
KH16-11847	14
KH16-11859	0
KH16-11861	10
KH16-12588	0
KH16-12589	0
KH16-12591	8
KH16-12592	1
KH16-12595	0
KH16-12596	9
KH16-12598	1
KH16-12601	5
KH16-07730	1
KH16-07731	7
KH16-07733	2
KH16-07736	7
KH16-07737	0
KH16-07738	0
KH16-07739	18
KH16-07743	6
KH16-07747	17
KH16-07748	0

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1244984	1
BRH1244985	0
BRH1244986	0
BRH1244987	0
BRH1244988	1
BRH1244989	1
BRH1244990	0
BRH1244991	1
BRH1244992	0
BRH1244993	0
BRH1244994	0
BRH1244995	0
BRH1244996	0
BRH1244997	0
BRH1244998	2
BRH1244999	0
BRH1245000	1
BRH1245001	0
BRH1245002	1
BRH1245003	0
BRH1245004	0
BRH1245005	0
BRH1245006	0
BRH1245007	0
BRH1245008	11
BRH1245009	5
BRH1245010	0
BRH1245011	3
BRH1245012	0
BRH1245013	4
BRH1245014	0
BRH1245015	0
BRH1245016	3
BRH1245017	0
BRH1245018	0
BRH1245019	0
BRH1245020	1
BRH1245021	0
BRH1245022	5
BRH1245023	0
BRH1245024	1
BRH1245025	2
BRH1245026	0

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
KH16-08310	5
KH16-08311	3
KH16-08312	8
KH16-08313	5
KH16-08315	3
KH16-08316	4
KH16-08317	18
KH16-08318	3
KH16-08319	1
KH16-08320	7
KH16-08321	6
KH16-08322	4
KH16-08325	9

No of Observations	140
Average Number	3.7
Median Number	2

# of Patients w/ 0 Pos Results	43
% Subjects w/ 0 pos results	30.7

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1245027	3
BRH1245029	0
BRH1245030	0
BRH1245031	0
BRH1245032	0
BRH1245033	0
BRH1245034	2
BRH1245035	0
BRH1245036	6
BRH1245037	0
BRH1245038	5
BRH1245039	2
BRH1245040	0
BRH1245041	0
BRH1267320	0
BRH1267321	4
BRH1267322	2
BRH1267323	1
BRH1267327	1
BRH1267329	1
BRH1267330	0
BRH1267331	1
BRH1267333	0
BRH1267334	3
BRH1267335	3
BRH1267337	2
BRH1267338	0
BRH1267339	3
BRH1267340	4
BRH1267341	0
BRH1267342	0
BRH1267343	6
BRH1267345	0
BRH1267346	0
BRH1267347	0
BRH1267349	0

No of Observations	163
Average Number	1.2

DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile

NON-DYSPEPSIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
Median Number	0

# of Patients w/ 0 Pos Results	97
% Subjects w/ 0 pos results	59.5

Table 5B

Summary statistics

Variable	Dyspepsia_90th_percentile
Sample size	140
Lowest value	0.0000
Highest value	24.0000
Arithmetic mean	5.5357
95% CI for the mean	4.5851 to 6.4864
Median	4.0000
95% CI for the median	3.0000 to 5.0000
Variance	32.3656
Standard deviation	5.6891
Relative standard deviation	1.0277 (102.77%)
Standard error of the mean	0.4808
Coefficient of Skewness	1.2464 (P<0.0001)
Coefficient of Kurtosis	0.8545 (P=0.0726)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

Percentiles		95% Confidence interval
2.5	0.0000	
5	0.0000	0.0000 to 0.0000
10	0.0000	0.0000 to 0.0000
25	1.0000	0.7212 to 2.0000
75	8.5000	6.0000 to 11.0000
90	14.0000	12.2003 to 18.0000
95	18.0000	14.0699 to 20.1768
97.5	20.0000	

Table 6A

Summary statistics

Variable	Dyspepsia_95th_percentile
Sample size	140
Lowest value	0.0000
Highest value	19.0000
Arithmetic mean	3.6714
95% CI for the mean	2.9083 to 4.4345
Median	2.0000
95% CI for the median	1.0000 to 3.0000
Variance	20.8553
Standard deviation	4.5668
Relative standard deviation	1.2439 (124.39%)
Standard error of the mean	0.3860
Coefficient of Skewness	1.6039 (P<0.0001)
Coefficient of Kurtosis	2.1657 (P=0.0014)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

Percentiles		95% Confidence interval
2.5	0.0000	
5	0.0000	0.0000 to 0.0000
10	0.0000	0.0000 to 0.0000
25	0.0000	0.0000 to 1.0000
75	5.0000	4.2448 to 7.0000
90	10.0000	7.2003 to 14.0329
95	14.5000	11.0000 to 18.0000
97.5	18.0000	

Table 6B

Summary statistics

Variable	Non_Dyspepsia_90th_percentile
Sample size	163
Lowest value	0.0000
Highest value	21.0000
Arithmetic mean	2.5460
95% CI for the mean	1.9544 to 3.1377
Median	1.0000
95% CI for the median	1.0000 to 1.0000
Variance	14.6321
Standard deviation	3.8252
Relative standard deviation	1.5024 (150.24%)
Standard error of the mean	0.2996
Coefficient of Skewness	2.1855 (P<0.0001)
Coefficient of Kurtosis	5.1288 (P<0.0001)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

Percentiles		95% Confidence interval
2.5	0.0000	0.0000 to 0.0000
5	0.0000	0.0000 to 0.0000
10	0.0000	0.0000 to 0.0000
25	0.0000	0.0000 to 0.0000
75	4.0000	2.0000 to 5.0000
90	8.0000	5.0000 to 11.0000
95	11.0000	8.5173 to 15.0000
97.5	13.8500	11.0000 to 20.1461

Table 7A

Summary statistics

Variable	Non_Dyspepsia_95th_percentile Non-Dyspepsia 95th percentile
Sample size	163
Lowest value	0.0000
Highest value	13.0000
Arithmetic mean	1.2331
95% CI for the mean	0.8815 to 1.5847
Median	0.0000
95% CI for the median	0.0000 to 0.0000
Variance	5.1675
Standard deviation	2.2732
Relative standard deviation	1.8435 (184.35%)
Standard error of the mean	0.1781
Coefficient of Skewness	2.6699 (P<0.0001)
Coefficient of Kurtosis	8.1925 (P<0.0001)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

Percentiles		95% Confidence interval
2.5	0.0000	0.0000 to 0.0000
5	0.0000	0.0000 to 0.0000
10	0.0000	0.0000 to 0.0000
25	0.0000	0.0000 to 0.0000
75	1.0000	1.0000 to 2.0000
90	4.0000	3.0000 to 6.0000
95	6.0000	5.0000 to 9.6282
97.5	7.8500	6.0000 to 12.5731

Table 7B

Variable	Dyspepsia_90th_percentile_1	
Back-transformed after logarithmic transformation.		
Sample size		140
Lowest value		0.1000
Highest value		24.0000
Geometric mean		2.3622
95% CI for the mean		1.7821 to 3.1312
Median		4.0000
95% CI for the median		3.0000 to 5.0000
Coefficient of Skewness		-0.8759 (P=0.0001)
Coefficient of Kurtosis		-0.3090 (P=0.3343)
D'Agostino-Pearson test for Normal distribution		reject Normality (P=0.0003)
Percentiles		95% Confidence interval
2.5	0.10000	
5	0.10000	0.10000 to 0.10000
10	0.10000	0.10000 to 0.10000
25	1.0000	0.5253 to 2.0000
75	8.4853	6.0000 to 11.0000
90	14.0000	12.1940 to 18.0000
95	18.0000	14.0677 to 20.2603
97.5	20.1000	

Table 8A

Summary statistics

Variable	Dyspepsia_95th_percentile_1	
Back-transformed after logarithmic transformation.		
Sample size		140
Lowest value		0.1000
Highest value		19.0000
Geometric mean		1.1926
95% CI for the mean		0.8788 to 1.6190
Median		2.0000
95% CI for the median		1.0000 to 3.0000
Coefficient of Skewness		-0.3072 (P=0.1313)
Coefficient of Kurtosis		-1.4004 (P<0.0001)
D'Agostino-Pearson test for Normal distribution		reject Normality (P<0.0001)
Percentiles		95% Confidence interval
2.5	0.10000	
5	0.10000	0.10000 to 0.10000
10	0.10000	0.10000 to 0.10000
25	0.10000	0.10000 to 1.0000
75	5.0000	4.2246 to 7.0000
90	10.1000	7.1898 to 14.0318
95	14.4914	11.0000 to 18.0000
97.5	18.0000	

Table 8B

Summary statistics

Variable	Non_Dyspepsia_90th_percentile_1
Back-transformed after logarithmic transformation.	
Sample size	163
Lowest value	0.1000
Highest value	21.0000
Geometric mean	0.7479
95% CI for the mean	0.5686 to 0.9837
Median	1.0000
95% CI for the median	1.0000 to 1.0000
Coefficient of Skewness	0.04842 (P=0.7946)
Coefficient of Kurtosis	-1.4773 (P<0.0001)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

Percentiles		95% Confidence interval
2.5	0.10000	0.10000 to 0.10000
5	0.10000	0.10000 to 0.10000
10	0.10000	0.10000 to 0.10000
25	0.10000	0.10000 to 0.10000
75	4.0000	2.0000 to 5.0000
90	8.0000	5.0000 to 11.0000
95	11.0000	8.5026 to 15.0000
97.5	13.8152	11.0000 to 20.0738

Table 9A

Summary statistics

Variable	Non_Dyspepsia_95th_percentile_1
Back-transformed after logarithmic transformation.	
Sample size	163
Lowest value	0.1000
Highest value	13.0000
Geometric mean	0.3510
95% CI for the mean	0.2739 to 0.4499
Median	0.10000
95% CI for the median	0.10000 to 0.10000
Coefficient of Skewness	0.6871 (P=0.0007)
Coefficient of Kurtosis	-1.1515 (P<0.0001)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

Percentiles		95% Confidence interval
2.5	0.10000	0.10000 to 0.10000
5	0.10000	0.10000 to 0.10000
10	0.10000	0.10000 to 0.10000
25	0.10000	0.10000 to 0.10000
75	1.0000	1.0000 to 2.0000
90	4.0000	3.0000 to 6.0000
95	6.0000	5.0000 to 8.5855
97.5	7.7890	6.0000 to 12.5446

Table 9B

Independent samples t-test

Sample 1		
Variable	Dyspepsia_90th_percentile_1	
Sample 2		
Variable	Non_Dyspepsia_90th_percentile_1	
Back-transformed after logarithmic transformation.		
	Sample 1	Sample 2
Sample size	140	163
Geometric mean	2.3622	0.7479
95% CI for the mean	1.7821 to 3.1312	0.5686 to 0.9837
Variance of Logs	0.5365	0.5922
F-test for equal variances		P = 0.549

T-test (assuming equal variances)

Difference on Log-transformed scale	
Difference	-0.4995
Standard Error	0.08673
95% CI of difference	-0.6701 to -0.3288
Test statistic t	-5.759
Degrees of Freedom (DF)	301
Two-tailed probability	P < 0.0001
Back-transformed results	
Ratio of geometric means	0.3166
95% CI of ratio	0.2137 to 0.4690

Table 10A

Independent samples t-test

Sample 1		
Variable	Dyspepsia_95th_percentile_1	
Sample 2		
Variable	Non_Dyspepsia_95th_percentile_1	
Back-transformed after logarithmic transformation.		
	Sample 1	Sample 2
Sample size	140	163
Geometric mean	1.1928	0.3510
95% CI for the mean	0.8788 to 1.6190	0.2739 to 0.4499
Variance of Logs	0.5304	0.4854
F-test for equal variances		P = 0.109

T-test (assuming equal variances)

Difference on Log-transformed scale	
Difference	-0.5313
Standard Error	0.08564
95% CI of difference	-0.6998 to -0.3627
Test statistic t	-6.203
Degrees of Freedom (DF)	301
Two-tailed probability	P < 0.0001
Back-transformed results	
Ratio of geometric means	0.2943
95% CI of ratio	0.1995 to 0.4338

Table 10B

Mann-Whitney test (independent samples)

Sample 1	
Variable	Dyspepsia_90th_percentile
Sample 2	
Variable	Non_Dyspepsia_90th_percentile

	Sample 1	Sample 2
Sample size	140	163
Lowest value	0.0000	0.0000
Highest value	24.0000	21.0000
Median	4.0000	1.0000
95% CI for the median	3.0000 to 5.0000	1.0000 to 1.0000
Interquartile range	1.0000 to 8.5000	0.0000 to 4.0000

Mann-Whitney test (independent samples)

Average rank of first group	182.6286
Average rank of second group	125.6933
Mann Whitney U	7122.00
Test statistic Z (corrected for ties)	5.727
Two-tailed probability	P < 0.0001

Table 11A

Mann-Whitney test (independent samples)

Sample 1	
Variable	Dyspepsia_95th_percentile
Sample 2	
Variable	Non_Dyspepsia_95th_percentile

	Sample 1	Sample 2
Sample size	140	163
Lowest value	0.0000	0.0000
Highest value	19.0000	13.0000
Median	2.0000	0.0000
95% CI for the median	1.0000 to 3.0000	0.0000 to 0.0000
Interquartile range	0.0000 to 5.0000	0.0000 to 1.0000

Mann-Whitney test (independent samples)

Average rank of first group	182.2750
Average rank of second group	125.9969
Mann Whitney U	7171.50
Test statistic Z (corrected for ties)	5.882
Two-tailed probability	P < 0.0001

Table 11B

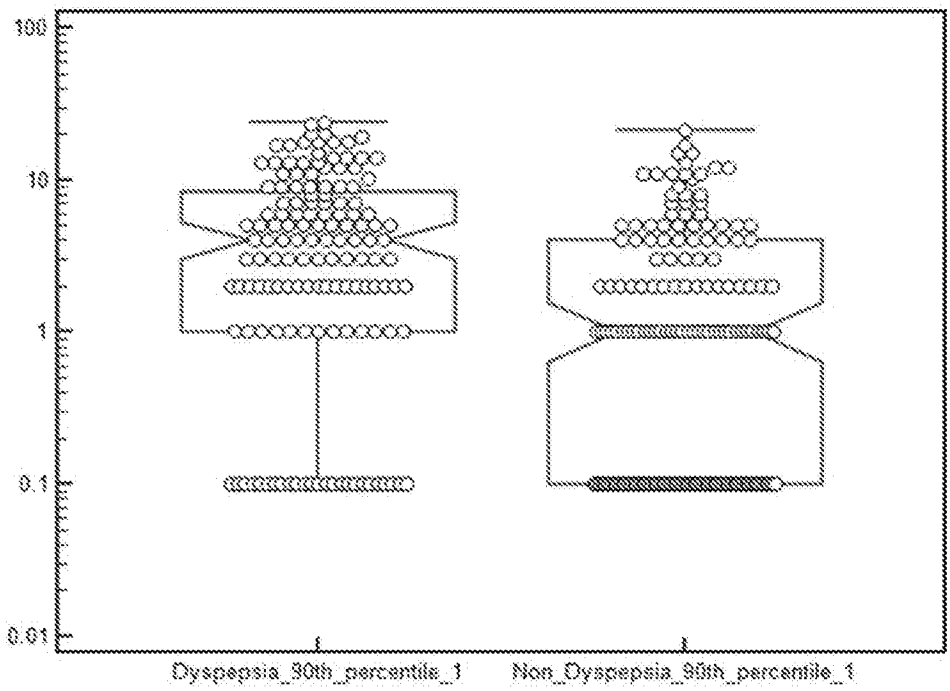


Figure 6A

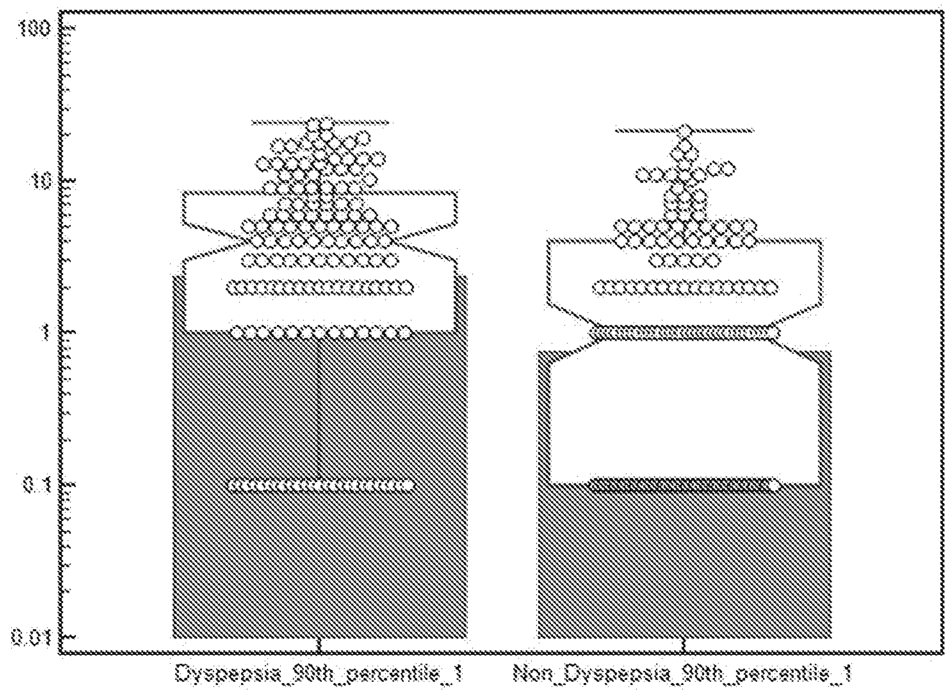


Figure 6B

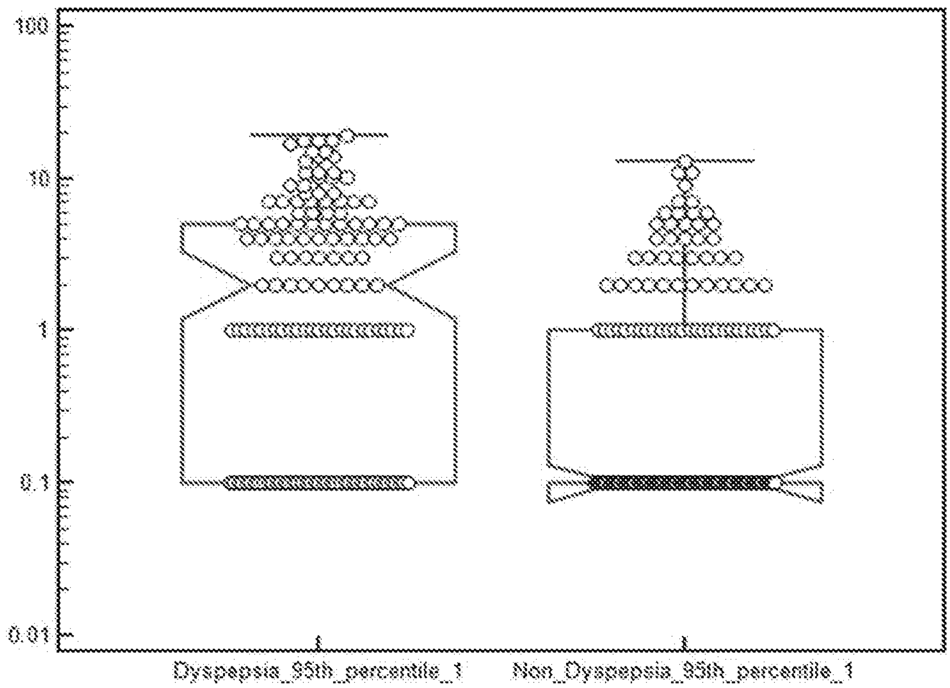


Figure 6C

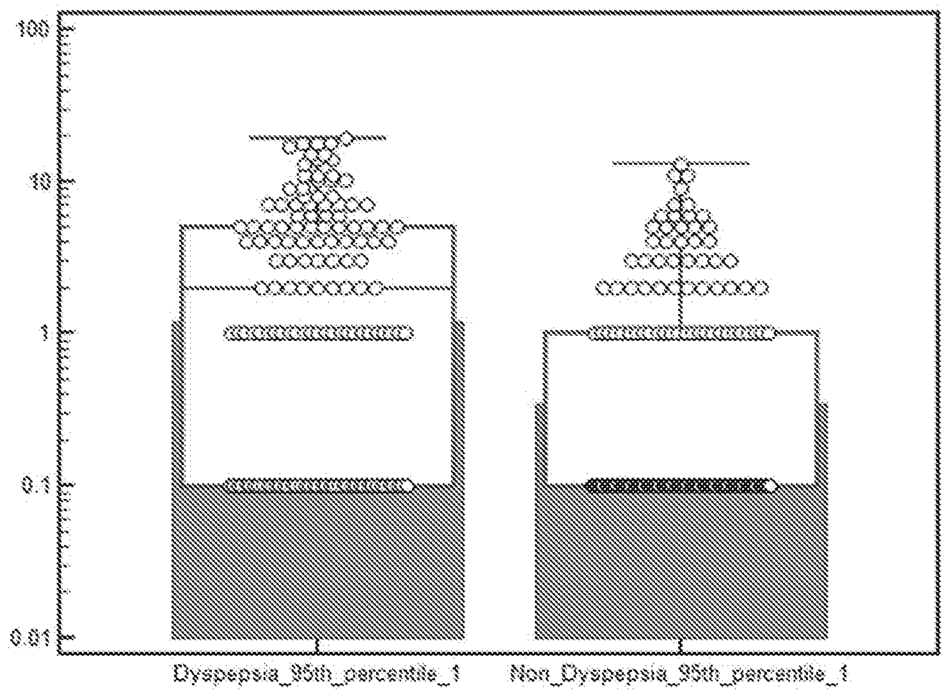


Figure 6D

ROC curve

Variable	Dyspepsia_Test Dyspepsia Test
Classification variable	Diagnosis__1_Dyspepsia__0_Non_Dyspepsia_ Diagnosis(1_Dyspepsia 0_Non-Dyspepsia)
Sample size	303
Positive group [a]	140 (46.20%)
Negative group [b]	163 (53.80%)

[a] Diagnosis__1_Dyspepsia__0_Non_Dyspepsia_ = 1
[b] Diagnosis__1_Dyspepsia__0_Non_Dyspepsia_ = 0

Disease prevalence (%)	unknown

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.688
Standard Error [a]	0.0302
95% Confidence interval [b]	0.632 to 0.740
z statistic	6.220
Significance level P (Area=0.5)	<0.0001

[a] DeLong et al., 1988
[b] Binomial exact

Youden index

Youden index J	0.3298
95% Confidence interval [a]	0.2210 to 0.4276
Associated criterion	>1
95% Confidence interval [a]	>1 to >2
Sensitivity	72.86
Specificity	60.12

[a] BC_a bootstrap confidence interval (1000 iterations; random number seed: 978)

Table 12A

ROC curve

Variable	Dyspepsia_Test Dyspepsia Test
Classification variable	Diagnosis__1_Dyspepsia__0_Non_Dyspepsia_ Diagnosis(1_Dyspepsia 0_Non-Dyspepsia)
Sample size	303
Positive group [a]	140 (46.20%)
Negative group [b]	163 (53.80%)

[a] Diagnosis__1_Dyspepsia__0_Non_Dyspepsia_ = 1
[b] Diagnosis__1_Dyspepsia__0_Non_Dyspepsia_ = 0

Disease prevalence (%)	unknown

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.686
Standard Error [a]	0.0292
95% Confidence interval [b]	0.630 to 0.738
z statistic	6.358
Significance level P (Area=0.5)	<0.0001

[a] DeLong et al., 1988
[b] Binomial exact

Youden index

Youden index J	0.2879
95% Confidence interval [a]	0.1775 to 0.3689
Associated criterion	>0
95% Confidence interval [a]	>0 to >2
Sensitivity	69.29
Specificity	59.51

[a] BC_a bootstrap confidence interval (1000 iterations; random number seed: 978).

Table 12B

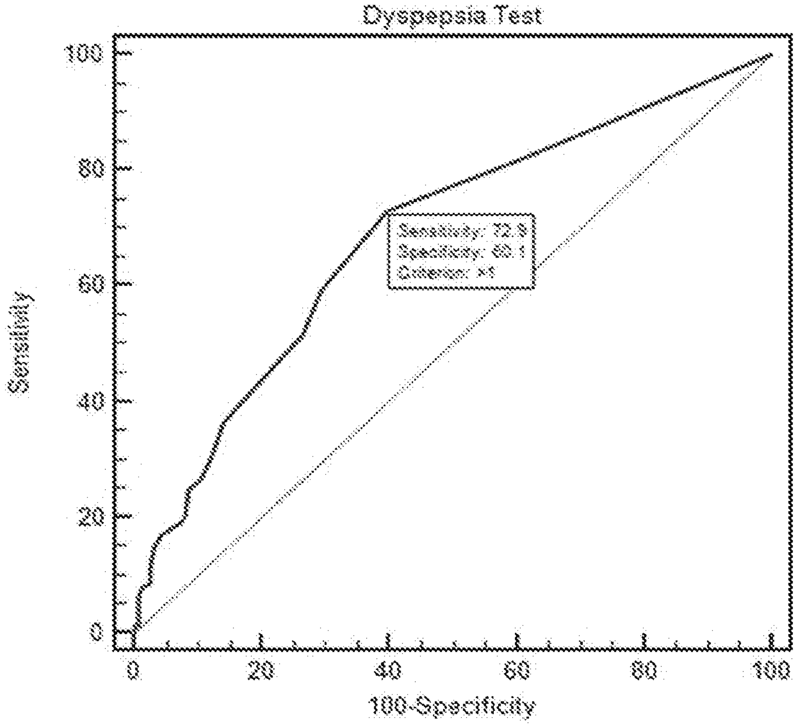

Dyspepsia Test
Sensitivity
100
80
60
40
20
0
0
20
40
60
80
100
100-Specificity
Sensitivity: 72.9
Specificity: 60.1
Criterion: >1

Figure 7A

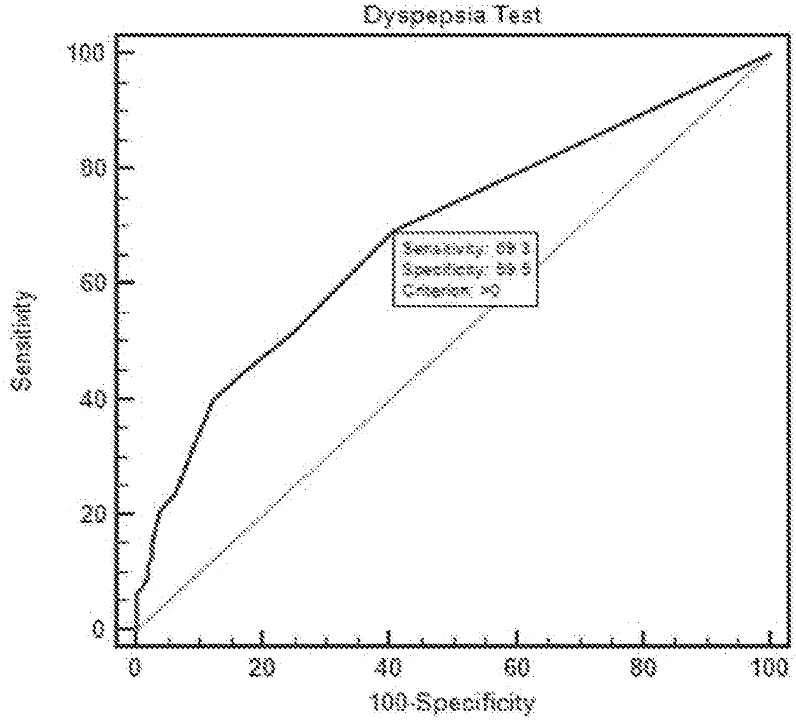

Dyspepsia Test
Sensitivity
100-Specificity
0
20
40
60
80
100
Sensitivity: 69.3
Specificity: 59.5
Criterion: >0

Figure 7B

Performance Metrics in Predicting Functional Dyspepsia Status from Number of Positive Foods

Using 90th Percentile of ELISA Signal to determine Positive

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
FEMALE	1	0.85	0.29	0.57	0.65	0.58
	2	0.80	0.45	0.61	0.68	0.63
	3	0.72	0.55	0.63	0.65	0.64
	4	0.68	0.61	0.65	0.63	0.64
	5	0.63	0.65	0.66	0.62	0.64
	6	0.57	0.69	0.67	0.60	0.63
	7	0.53	0.73	0.68	0.59	0.63
	8	0.48	0.79	0.71	0.58	0.63
	9	0.44	0.83	0.74	0.58	0.63
	10	0.40	0.86	0.75	0.57	0.62
	11	0.37	0.88	0.76	0.56	0.61
	12	0.33	0.90	0.77	0.55	0.60
	13	0.29	0.91	0.79	0.54	0.59
	14	0.26	0.93	0.80	0.54	0.58
	15	0.23	0.93	0.80	0.53	0.57
	16	0.21	0.95	0.82	0.53	0.56
	17	0.18	0.95	0.83	0.52	0.56
	18	0.16	0.97	0.86	0.52	0.55
	19	0.15	0.98	0.86	0.51	0.54
	20	0.13	0.98	0.88	0.51	0.54
	21	0.11	1.00	1.00	0.51	0.53
	22	0.10	1.00	1.00	0.51	0.53
	23	0.09	1.00	1.00	0.50	0.52
	24	0.09	1.00	1.00	0.50	0.52
	25	0.08	1.00	1.00	0.50	0.52
	26	0.07	1.00	1.00	0.50	0.52
	27	0.05	1.00	1.00	0.49	0.51
	28	0.04	1.00	1.00	0.49	0.50
	29	0.04	1.00	1.00	0.49	0.50
	30	0.02	1.00	1.00	0.49	0.49
	31	0.02	1.00	1.00	0.49	0.49
	32	0.00	1.00	1.00	0.48	0.49

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
	33	0.00	1.00	1.00	0.48	0.48
	34	0.00	1.00	1.00	0.48	0.48
	35	0.00	1.00	1.00	0.48	0.48
	36	0.00	1.00	1.00	0.48	0.48
	37	0.00	1.00	1.00	0.48	0.48

Table 13A

Performance Metrics in Predicting Functional Dyspepsia Status from Number of Positive Foods Using 90th Percentile of ELISA Signal to determine Positive

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
MALE	1	0.93	0.27	0.47	0.83	0.54
	2	0.80	0.42	0.50	0.75	0.58
	3	0.67	0.56	0.53	0.71	0.61
	4	0.57	0.67	0.55	0.69	0.63
	5	0.50	0.74	0.58	0.68	0.64
	6	0.44	0.78	0.59	0.67	0.64
	7	0.38	0.81	0.59	0.65	0.64
	8	0.31	0.84	0.58	0.63	0.62
	9	0.26	0.88	0.59	0.63	0.62
	10	0.22	0.89	0.59	0.62	0.61
	11	0.19	0.90	0.56	0.61	0.60
	12	0.16	0.91	0.55	0.60	0.60
	13	0.15	0.91	0.55	0.60	0.59
	14	0.13	0.92	0.55	0.60	0.59
	15	0.11	0.93	0.55	0.60	0.59
	16	0.10	0.94	0.56	0.60	0.59
	17	0.09	0.95	0.57	0.60	0.59
	18	0.09	0.95	0.57	0.59	0.59
	19	0.08	0.96	0.57	0.59	0.59
	20	0.08	0.97	0.60	0.60	0.59
	21	0.08	0.97	0.60	0.60	0.60
	22	0.07	0.97	0.63	0.60	0.60
	23	0.07	0.97	0.67	0.60	0.60
	24	0.07	0.97	0.67	0.59	0.60
	25	0.06	0.98	0.67	0.59	0.60
	26	0.05	0.98	0.67	0.59	0.59
	27	0.05	0.98	0.67	0.59	0.59
	28	0.04	0.98	0.67	0.59	0.59
	29	0.03	0.98	0.67	0.59	0.59
	30	0.02	0.99	0.67	0.59	0.59
	31	0.02	1.00	1.00	0.59	0.59

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
	32	0.02	1.00	1.00	0.59	0.59
	33	0.02	1.00	1.00	0.59	0.59
	34	0.02	1.00	1.00	0.59	0.59
	35	0.02	1.00	1.00	0.59	0.59
	36	0.00	1.00	1.00	0.59	0.59
	37	0.00	1.00	1.00	0.58	0.59

Table 13B

Performance Metrics in Predicting Dyspepsia Status from Number of Positive Foods Using 95th Percentile of ELISA Signal to determine Positive

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
FEMALE	1	0.80	0.43	0.60	0.67	0.62
	2	0.73	0.59	0.66	0.68	0.67
	3	0.64	0.67	0.68	0.64	0.66
	4	0.58	0.73	0.70	0.62	0.66
	5	0.50	0.78	0.71	0.59	0.64
	6	0.44	0.83	0.73	0.58	0.62
	7	0.38	0.87	0.76	0.57	0.62
	8	0.34	0.90	0.79	0.56	0.61
	9	0.30	0.93	0.81	0.55	0.60
	10	0.26	0.95	0.84	0.54	0.59
	11	0.21	0.97	0.88	0.53	0.58
	12	0.18	0.98	0.90	0.53	0.57
	13	0.16	0.98	0.91	0.52	0.56
	14	0.14	1.00	1.00	0.52	0.55
	15	0.13	1.00	1.00	0.51	0.54
	16	0.12	1.00	1.00	0.51	0.54
	17	0.11	1.00	1.00	0.51	0.54
	18	0.10	1.00	1.00	0.51	0.53
	19	0.09	1.00	1.00	0.51	0.53
	20	0.08	1.00	1.00	0.50	0.52
	21	0.07	1.00	1.00	0.50	0.52
	22	0.07	1.00	1.00	0.50	0.51
	23	0.05	1.00	1.00	0.49	0.51
	24	0.04	1.00	1.00	0.49	0.51
	25	0.02	1.00	1.00	0.49	0.49
	26	0.02	1.00	1.00	0.49	0.49
	27	0.02	1.00	1.00	0.48	0.49
	28	0.00	1.00	1.00	0.48	0.49
	29	0.00	1.00	1.00	0.48	0.48
	30	0.00	1.00	1.00	0.48	0.48
	31	0.00	1.00	1.00	0.48	0.48
	32	0.00	1.00	1.00	0.48	0.48
	33	0.00	1.00	1.00	0.48	0.48

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
	34	0.00	1.00	1.00	0.48	0.48
	35	0.00	1.00	.	0.48	0.48
	36	0.00	1.00	.	0.48	0.48
	37	0.00	1.00	.	0.48	0.48

Table 14A

Performance Metrics in Predicting Dyspepsia Status from Number of Positive Foods Using 95th Percentile of ELISA Signal to determine Positive

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
MALE	1	0.76	0.42	0.48	0.71	0.56
	2	0.54	0.66	0.53	0.67	0.61
	3	0.43	0.78	0.58	0.66	0.64
	4	0.37	0.82	0.59	0.64	0.63
	5	0.30	0.85	0.60	0.63	0.63
	6	0.26	0.88	0.60	0.63	0.62
	7	0.21	0.90	0.59	0.62	0.61
	8	0.17	0.92	0.59	0.61	0.61
	9	0.15	0.93	0.60	0.61	0.61
	10	0.12	0.94	0.57	0.60	0.60
	11	0.10	0.95	0.57	0.60	0.60
	12	0.09	0.95	0.60	0.60	0.60
	13	0.08	0.96	0.60	0.60	0.60
	14	0.08	0.97	0.67	0.60	0.60
	15	0.07	0.98	0.67	0.60	0.60
	16	0.07	0.98	0.71	0.60	0.60
	17	0.07	0.98	0.75	0.60	0.60
	18	0.06	0.98	0.75	0.60	0.60
	19	0.05	0.98	0.75	0.59	0.60
	20	0.05	0.99	0.75	0.59	0.60
	21	0.04	1.00	1.00	0.59	0.60
	22	0.04	1.00	1.00	0.59	0.60
	23	0.03	1.00	1.00	0.59	0.60
	24	0.02	1.00	1.00	0.59	0.60
	25	0.02	1.00	1.00	0.59	0.60
	26	0.02	1.00	1.00	0.59	0.59
	27	0.02	1.00	1.00	0.59	0.59
	28	0.02	1.00	1.00	0.59	0.59
	29	0.02	1.00	1.00	0.59	0.59
	30	0.02	1.00	1.00	0.59	0.59
	31	0.00	1.00	1.00	0.59	0.59
	32	0.00	1.00	1.00	0.59	0.59
	33	0.00	1.00	1.00	0.59	0.59

Sex	*No. of Positive Foods as Cutoff*	*Sensitivity*	*Specificity*	*Positive Predictive Value*	*Negative Predictive Value*	*Overall Percent Agreement*
	34	0.00	1.00	1.00	0.58	0.59
	35	0.00	1.00	1.00	0.58	0.58
	36	0.00	1.00	1.00	0.58	0.58
	37	0.00	1.00	.	0.58	0.58

Table 14B

INTERNATIONAL SEARCH REPORT	International application No. **PCT/US2017/021643**

A. CLASSIFICATION OF SUBJECT MATTER

G01N 33/543(2006.01)i, G01N 33/564(2006.01)i, A61B 5/00(2006.01)i

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)
G01N 33/543; C12Q 1/02; G01N 33/53; C12M 3/00; G01N 33/564; A61B 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords:food intolerance, Functional Dyspepsia, distinct food preparation, average discriminatory p-value, gender identification, IgG, ELISA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ZUO, X. L. et al., "Alterations of food antigen-specific serum immunoglobulins G and E antibodies in patients with irritable bowel syndrome and functional dyspepsia" , Clinical and Experimental Allergy, 2007, Vol. 37, No.6, pp. 823-830 See abstract; pages 824, 825; table 1; and figure 1.	1-10,12,14,16,18,20,22,24,26-30,32,34,36,38,40,42,44,46-54,56,58,60,62,64,66,68,70,72,74-83,85,87,89,91,93,95,97,100
A	ZENG, Q. et al., "Variable Food-Specific IgG Antibody Levels in Healthy and Symptomatic Chinese Adults" , PLOS ONE, 2013, Vol. 8, No. 11, e53612, internal pages 1-9 See the whole document.	1-10,12,14,16,18,20,22,24,26-30,32,34,36,38,40,42,44,46-54,56,58,60,62,64,66,68,70,72,74-83,85,87,89,91,93,95,97,100

☒ 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	Date of mailing of the international search report
30 June 2017 (30.06.2017)	**30 June 2017 (30.06.2017)**

Name and mailing address of the ISA/KR	Authorized officer
International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea	CHO, Ki Yun
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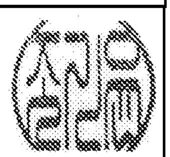

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/021643

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.: See supplemental Box.
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 addtional 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 an additional fees, this Authority did not invite payment of any 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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/021643

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010-0227340 A1 (ROZENSHTEYN, A. et al.) 09 September 2010 See the whole document.	1-10,12,14,16,18,20,22,24,26-30,32,34,36,38,40,42,44,46-54,56,58,60,62,64,66,68,70,72,74-83,85,87,89,91,93,95,97,100
A	US 2007-0122840 A1 (COUSINS, P. D. G.) 31 May 2007 See the whole document.	1-10,12,14,16,18,20,22,24,26-30,32,34,36,38,40,42,44,46-54,56,58,60,62,64,66,68,70,72,74-83,85,87,89,91,93,95,97,100
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Claims Nos.: 11, 13, 15, 17, 19, 21, 23, 25, 31, 33, 35, 37, 39, 41, 43, 45, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 84, 86, 88, 90, 92, 94, 96, 98, 99