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(54) Titre : COMPOSITIONS, DISPOSITIFS, ET PROCEDES D'EVALUATION DE LA SENSIBILITE A LA FIBROMYALGIE
(54) Title: COMPOSITIONS, DEVICES, AND METHODS OF FIBROMYALGIA SENSITIVITY TESTING

*Distribution of ELISA Signal Scores by Diagnosis
Sex=MALE Food=Almond*

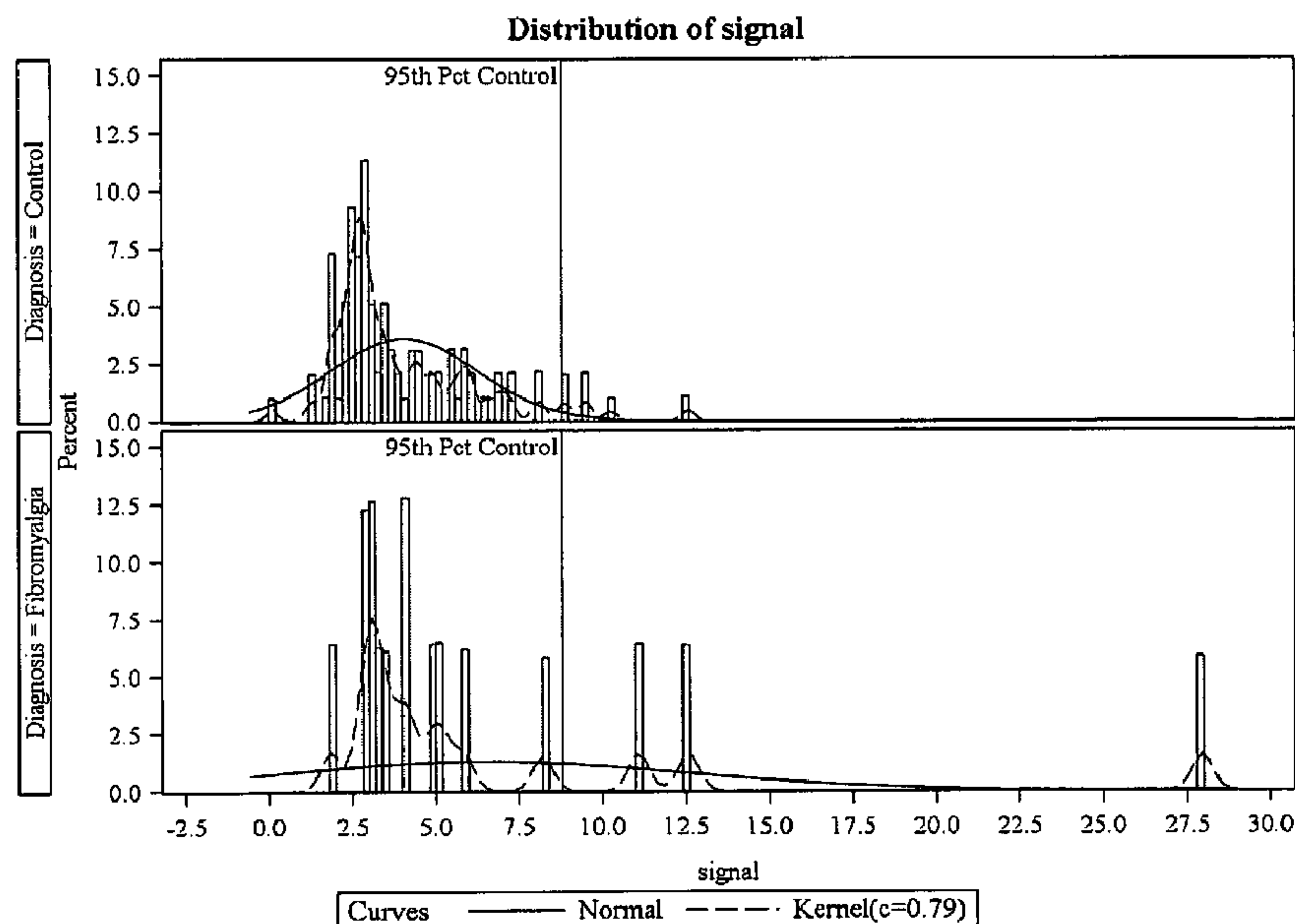


Figure 1A

(57) **Abrégé/Abstract:**

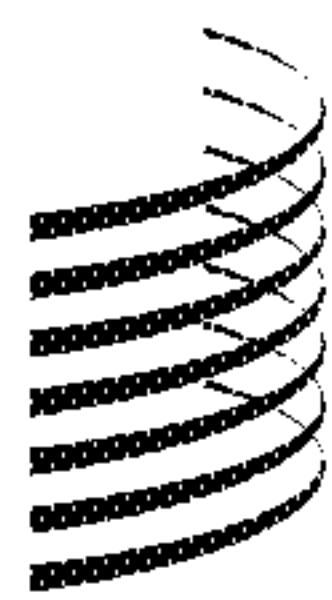
Contemplated test kits and methods for food sensitivity are based on rational-based selection of food preparations with established discriminatory p-value. Particularly preferred kits include those with a minimum number of food preparations that have an average

(57) **Abrégé(suite)/Abstract(continued):**

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.

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

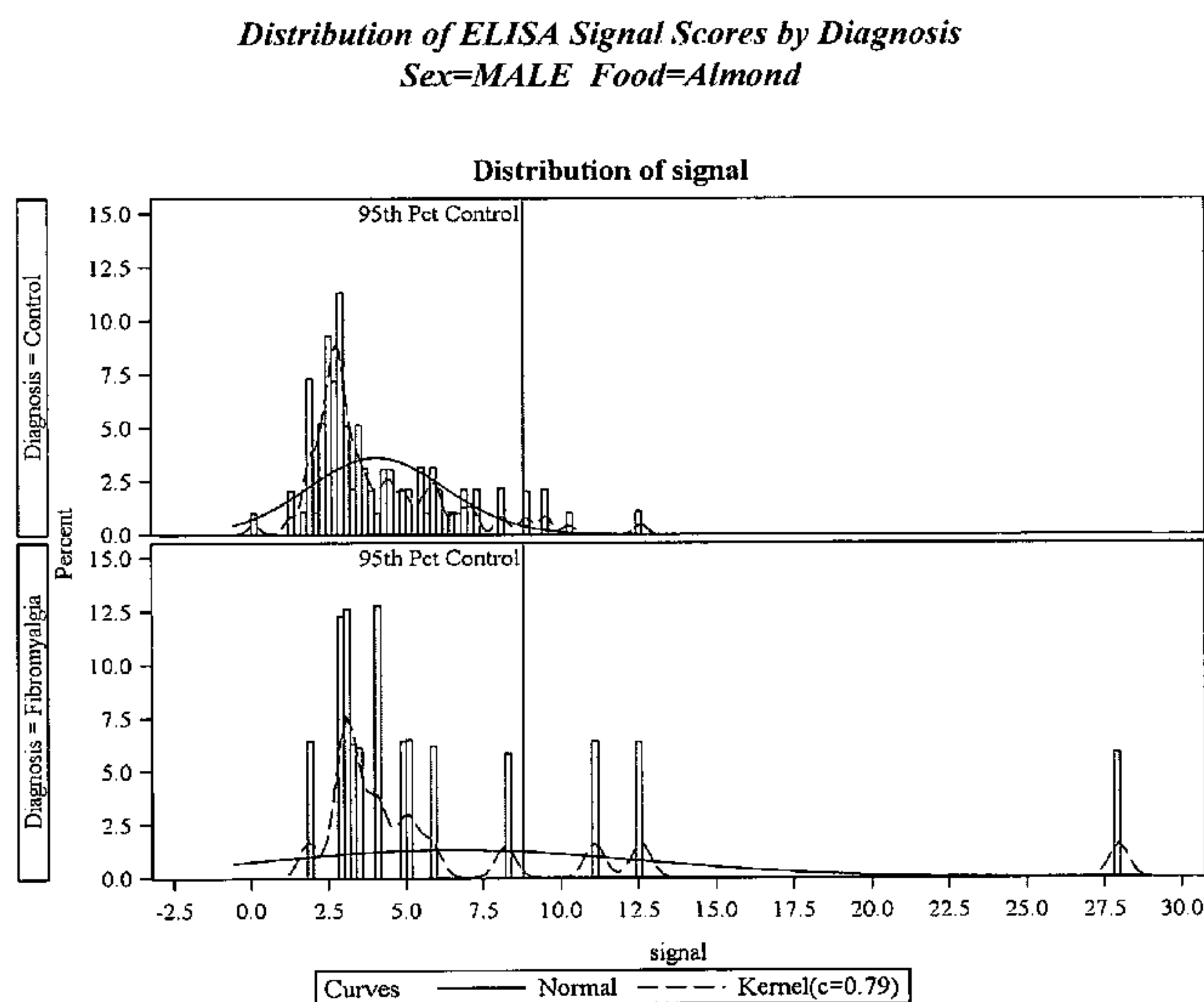


Figure 1A

(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.

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COMPOSITIONS, DEVICES, AND METHODS OF FIBROMYALGIA SENSITIVITY TESTING

Related Applications

[0001] This application claims priority to our U.S. provisional patent application with the
5 serial number 62/308348, filed March 15, 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
10 patients diagnosed with or suspected to have Fibromyalgia.

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
15 implicitly referenced is prior art.

[0004] Food sensitivity, especially as it relates to Fibromyalgia (a type of central sensitization syndrome), often presents with chronic widespread pain, allodynia, debilitating fatigue, sleep disturbance, joint stiffness, and underlying causes of Fibromyalgia are not well understood in the medical community. There is no single test that can fully diagnose
20 Fibromyalgia. There is no universally accepted treatment or cure for Fibromyalgia. Furthermore, currently available methods for managing the symptoms have only small to moderate effect to reducing symptoms for Fibromyalgia. Elimination of other one or more food items has also shown promise in at least reducing incidence and/or severity of the symptoms. However, Fibromyalgia is often quite diverse with respect to dietary items
25 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
5 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 Fibromyalgia patients show positive response to food A, and not all Fibromyalgia patients show negative response to food B. Thus, even if a Fibromyalgia patient shows positive response to food A, removal of food A from the
10 patient's diet may not relieve the patient's Fibromyalgia 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 Fibromyalgia.

[0006] All publications identified herein are incorporated by reference to the same extent as
15 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 Fibromyalgia.

25 Summary

[0008] The subject matter described herein provides systems and methods for testing food intolerance in patients diagnosed with or suspected to have Fibromyalgia. One aspect of the disclosure is a test kit with for testing food intolerance in patients diagnosed with or suspected to have Fibromyalgia. The test kit includes a plurality of distinct food preparations
30 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 Fibromyalgia with assay values of a second patient test cohort that is not diagnosed with or suspected of having Fibromyalgia.

5 [0009] Another aspect of the embodiments described herein includes a method of testing food intolerance in patients diagnosed with or suspected to have Fibromyalgia. 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 Fibromyalgia. The bodily fluid is associated with gender identification. In certain embodiments, the step of contacting is performed under conditions
10 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.

15 [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 Fibromyalgia. 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 Fibromyalgia and bodily fluids of a control group not diagnosed with or not suspected to
20 have Fibromyalgia. 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
25 of distinct food preparations coupled to individually addressable respective solid carriers in a diagnosis of Fibromyalgia. 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
30 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.

5 [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.

10 [0017] **Figure 1A** illustrates ELISA signal score of male Fibromyalgia patients and control tested with almond.

[0018] **Figure 1B** illustrates a distribution of percentage of male Fibromyalgia subjects exceeding the 90th and 95th percentile tested with almond.

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

15 [0020] **Figure 1D** illustrates a distribution of percentage of female Fibromyalgia subjects exceeding the 90th and 95th percentile tested with almond.

[0021] **Figure 2A** illustrates ELISA signal score of male Fibromyalgia patients and control tested with rye.

20 [0022] **Figure 2B** illustrates a distribution of percentage of male Fibromyalgia subjects exceeding the 90th and 95th percentile tested with rye.

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

[0024] **Figure 2D** illustrates a distribution of percentage of female Fibromyalgia subjects exceeding the 90th and 95th percentile tested with rye.

[0025] **Figure 3A** illustrates ELISA signal score of male Fibromyalgia patients and control tested with cantaloupe.

[0026] **Figure 3B** illustrates a distribution of percentage of male Fibromyalgia subjects exceeding the 90th and 95th percentile tested with cantaloupe.

5 [0027] **Figure 3C** illustrates a signal distribution in women along with the 95th percentile cutoff as determined from the female control population tested with cantaloupe.

[0028] **Figure 3D** illustrates a distribution of percentage of female Fibromyalgia subjects exceeding the 90th and 95th percentile tested with cantaloupe.

10 [0029] **Figure 4A** illustrates ELISA signal score of male Fibromyalgia patients and control tested with malt.

[0030] **Figure 4B** illustrates a distribution of percentage of male Fibromyalgia 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.

15 [0032] **Figure 4D** illustrates a distribution of percentage of female Fibromyalgia subjects exceeding the 90th and 95th percentile tested with malt.

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

20 [0034] **Figure 5B** illustrates distributions of Fibromyalgia subjects by number of foods that were identified as trigger foods at the 95th percentile.

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

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

25 [0037] **Table 6A** shows statistical data summarizing the raw data of Fibromyalgia patient populations shown in Table 5A.

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

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

5 [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 Fibromyalgia patient populations shown in Table 5A transformed by logarithmic transformation.

10 [0042] **Table 8B** shows statistical data summarizing the raw data of Fibromyalgia 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.

15 [0045] **Table 10A** shows statistical data of an independent T-test to compare the geometric mean number of positive foods between the Fibromyalgia and non-Fibromyalgia samples based on the 90th percentile.

20 [0046] **Table 10B** shows statistical data of an independent T-test to compare the geometric mean number of positive foods between the Fibromyalgia and non-Fibromyalgia samples based on the 95th percentile.

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

25 [0048] **Table 11B** shows statistical data of a Mann-Whitney test to compare the geometric mean number of positive foods between the Fibromyalgia and non-Fibromyalgia samples based on the 95th 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.

5 [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.

10 [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 Fibromyalgia status among female patients from number of positive foods based on the 90th percentile.

15 [0058] **Table 13B** shows a statistical data of performance metrics in predicting Fibromyalgia status among male patients from number of positive foods based on the 90th percentile.

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

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

20 **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 Fibromyalgia are not equally well predictive and/or associated with Fibromyalgia/Fibromyalgia symptoms. Indeed, various experiments have revealed that among a wide variety of food items certain food items
25 are highly predictive/associated with Fibromyalgia whereas others have no statistically significant association with Fibromyalgia.

[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 of a food item with Fibromyalgia. 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 Fibromyalgia 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
5 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.

10 [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
15 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 Fibromyalgia. Most preferably, such test kit or panel will include a
20 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 $\leq$ 0.07 as determined by raw p-value or an average discriminatory p-value of $\leq$ 0.10 as
25 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
30 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
5 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
10 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 Fibromyalgia. Particularly suitable food preparations may be identified by the experimental
15 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 1-43 of Table 2. Still further especially contemplated food items and food additives from which food
20 preparations can be prepared are listed in **Table 1**.

[0071] Using bodily fluids from patients diagnosed with or suspected to have Fibromyalgia and healthy control group individuals (*i.e.*, those not diagnosed with or not suspected to have Fibromyalgia), 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
25 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
30 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 Fibromyalgia. 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
5 suspected to have Fibromyalgia, 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
10 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,
15 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 1-43 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
20 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
25 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
30 (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.

5 [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 Fibromyalgia. Because the test is applied to patients already diagnosed with or suspected to have Fibromyalgia, 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
 10 suspected Fibromyalgia 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 Fibromyalgia and bodily fluids of a control group not diagnosed with or not suspected to have Fibromyalgia. Most preferably, the test results are then stratified by
 15 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
 20 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 1-43 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 1-43 of Table 2. Regardless of the particular choice of
 25 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.

30 [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 Fibromyalgia.

5 **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.

10 [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 Fibromyalgia 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
15 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
20 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.

[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,
25 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,
30 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] Blocking of ELISA plates: 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] ELISA preparation and sample testing: 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] Methodology to determine ranked food list in order of ability of ELISA signals to distinguish Fibromyalgia from control subjects: 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 of foods will be shorter than 50 food items, and more preferably equal to or less than 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, Fibromyalgia: 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 Fibromyalgia 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 Fibromyalgia 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, Fibromyalgia 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 Fibromyalgia subject in the bootstrap sample will be compared to the 90th and 95th 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 Fibromyalgia 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 almond 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 Fibromyalgia 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 Fibromyalgia subjects exceeding the 90th and 95th percentile. In the same fashion, **Figures 2A-2D** exemplarily depict the differential response to rye, **Figures 3A-3D** exemplarily depict the differential response to cantaloupe, and **Figures 4A-4D** exemplarily depict the differential response to malt. **Figures 5A-5B** show the distribution of Fibromyalgia 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 Fibromyalgia 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 Fibromyalgia patients have been significantly improved.

[0096] Normalization of IgG Response Data: While the raw data of the patient's IgG

5 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
10 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

15 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
20 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
25 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.

30 [0098] Methodology to determine the subset of Fibromyalgia patients with food sensitivities that underlie Fibromyalgia: While it is suspected that food sensitivities plays a substantial role in signs and symptoms of Fibromyalgia, some Fibromyalgia patients may not have food

sensitivities that underlie Fibromyalgia. Those patients would not be benefit from dietary intervention to treat signs and symptoms of Fibromyalgia. To determine the subset of such patients, body fluid samples of Fibromyalgia patients and non- Fibromyalgia patients can be tested with ELISA test using test devices with up to 43 food samples.

5 [0099] **Table 5A** and **Table 5B** provide exemplary raw data. As should be readily appreciated, the data indicate number of positive results out of 43 sample foods based on 90th percentile value (**Table 5A**) or 95th percentile value (**Table 5B**). The first column is Fibromyalgia (n=120); second column is non-Fibromyalgia (n=163) by ICD-10 code. Average and median number of positive foods was computed for Fibromyalgia and non-
10 Fibromyalgia 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 Fibromyalgia and non-Fibromyalgia patients. Additionally, the number and percentage of patients with zero positive foods was calculated for both Fibromyalgia and non-Fibromyalgia. The number and percentage of patients with zero positive foods in the Fibromyalgia population is less than
15 half of the percentage of patients with zero positive foods in the non- Fibromyalgia population (15% vs. 31.3%, respectively) based on 90th percentile value (**Table 5A**), and the percentage of patients in the Fibromyalgia population with zero positive foods is also approximately half of that seen in the non-Fibromyalgia population (25 % vs. 46.6%, respectively) based on 95th percentile value (**Table 5B**). Thus, it can be easily appreciated that
20 the Fibromyalgia patient having sensitivity to zero positive foods is unlikely to have food sensitivities underlying their signs and symptoms of Fibromyalgia.

[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
25 median representing number of positive foods in the Fibromyalgia population and the non-Fibromyalgia 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 Fibromyalgia
30 population and the non-Fibromyalgia 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.

- 5 **[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 Fibromyalgia and non-Fibromyalgia 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
- 10 Fibromyalgia population and the non-Fibromyalgia population. In both statistical tests, it is shown that the number of positive responses with 43 food samples is significantly higher in the Fibromyalgia population than in the non-Fibromyalgia 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**.
- 15 **[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 Fibromyalgia and non-Fibromyalgia 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
- 20 Fibromyalgia population and the non-Fibromyalgia population. In both statistical tests, it is shown that the number of positive responses with 43 food samples is significantly higher in the Fibromyalgia population than in the non-Fibromyalgia 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**.
- 25 **[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 Fibromyalgia from non-Fibromyalgia subjects. When a cutoff criterion of more than 3 positive foods is used, the test yields a data with 55% sensitivity and 67.5% specificity, with an area under the curve
- 30 (AUROC) of 0.638. 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 Fibromyalgia population and the non-

Fibromyalgia population is significant when the test results are cut off to a positive number of 3, the number of foods for which a patient tests positive could be used as a confirmation of the primary clinical diagnosis of Fibromyalgia, and whether it is likely that food sensitivities underlies on the patient's signs and symptoms of Fibromyalgia. Therefore, the above test can be used as another 'rule in' test to add to currently available clinical criteria for diagnosis for Fibromyalgia.

[00105] As shown in Tables 5A-12A, and Figure 7A, based on 90th percentile data, the number of positive foods seen in Fibromyalgia vs. non-Fibromyalgia 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 Fibromyalgia in subjects. The test has discriminatory power to detect Fibromyalgia with ~55% sensitivity and ~68% specificity. Additionally, the absolute number and percentage of subjects with 0 positive foods is also very different in Fibromyalgia vs. non-Fibromyalgia subjects, with a far lower percentage of Fibromyalgia subjects (15%) having 0 positive foods than non-Fibromyalgia subjects (31.3%). The data suggests a subset of Fibromyalgia patients may have Fibromyalgia 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 Fibromyalgia from non-Fibromyalgia subjects. When a cutoff criterion of more than 1 positive foods is used, the test yields a data with 57.5% sensitivity and 68.1% specificity, with an area under the curve (AUROC) of 0.664. 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 Fibromyalgia population and the non-Fibromyalgia population is significant when the test results are cut off to positive number of >1, the number of foods that a patient tests positive could be used as a confirmation of the primary clinical diagnosis of Fibromyalgia, and whether it is likely that food sensitivities underlies on the patient's signs and symptoms of Fibromyalgia. Therefore, the above test can be used as another 'rule in' test to add to currently available clinical criteria for diagnosis for Fibromyalgia.

[00107] As shown in Tables 5B-12B, and Figure 7B, based on 95th percentile data, the number of positive foods seen in Fibromyalgia vs. non-Fibromyalgia 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 Fibromyalgia in subjects. The test has discriminatory power to detect Fibromyalgia with ~58% sensitivity and ~68% specificity. Additionally, the absolute number and percentage of subjects with 0 positive foods is also very different in Fibromyalgia vs. non-Fibromyalgia subjects, with a far lower percentage of Fibromyalgia subjects (~25%) having 0 positive foods than non-Fibromyalgia subjects (~47%). The data suggests a subset of Fibromyalgia patients may have Fibromyalgia due to other factors than diet, and may not benefit from dietary restriction.

[00108] Method for determining distribution of per-person number of foods declared

“positive”: To determine the distribution of number of “positive” foods per person and measure the diagnostic performance, the analysis will be performed with 43 food items from Table 2, which shows most positive responses to Fibromyalgia 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 Fibromyalgia 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 86 (43 foods x 2 cutpoints) calls for each subject will be saved within each bootstrap replicate. Then, for each subject, 24 calls will be summed using 90th percentile as cutpoint to get “Number of Positive Foods (90th),” and the rest of 43 calls will be summed using 95th percentile to get “Number of Positive Foods (95th).” Then, within each replicate, “Number of Positive Foods (90th)” and “Number of Positive Foods (95th)” 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 (90th)” and “Number of Positive Foods (95th)” for both genders and for both Fibromyalgia subjects and control subjects using programs

5 “a_pos_foods.sas, a_pos_foods_by_dx.sas”.

[00110] Method for measuring diagnostic performance: To measure diagnostic performance for each food items for each subject, we will use data of “Number of Positive Foods (90th)” and “Number of Positive Foods (95th)” for each subject within each bootstrap replicate described above. In this analysis, the cutpoint was set to 1. Thus, if a subject has one
10 or more “Number of Positive Foods (90th)”, then the subject will be called “Has Fibromyalgia.” If a subject has less than one “Number of Positive Foods (90th)”, then the subject will be called “Does Not Have Fibromyalgia.” 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
15 summarized across subjects to get the performance metrics of sensitivity, specificity, positive predictive value, and negative predictive value for both “Number of Positive Foods (90th)” and “Number of Positive Foods(95th)” 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
20 cutpoint from 2 up to 43, 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
30 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
5 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
10 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.

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 (<i>S. cerevisiae</i>)
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**

<i>Rank</i>	<i>Food</i>	<i>Raw p-value</i>	<i>FDR Multiplicity-adj p-value</i>
1	Almond	0.0001	0.0059
2	Rye	0.0002	0.0059
3	Cantaloupe	0.0002	0.0059
4	Malt	0.0003	0.0059
5	Green_Pea	0.0004	0.0068
6	Green_Pepper	0.0007	0.0099
7	Tomato	0.0011	0.0124
8	Orange	0.0011	0.0124
9	Cane_Sugar	0.0014	0.0131
10	Garlic	0.0015	0.0131
11	Carrot	0.0019	0.0155
12	Tobacco	0.0021	0.0156
13	Cottage_Ch_	0.0033	0.0226
14	Egg	0.0041	0.0262
15	Buck_Wheat	0.0053	0.0291
16	Grapefruit	0.0055	0.0291
17	Cauliflower	0.0058	0.0291
18	Lemon	0.0062	0.0291
19	Grape	0.0063	0.0291
20	Wheat	0.0066	0.0291
21	Butter	0.0068	0.0291
22	Sunflower_Sd	0.0075	0.0307
23	Cow_Milk	0.0086	0.0335
24	Cheddar_Ch_	0.0100	0.0343
25	Broccoli	0.0101	0.0343
26	Cucumber	0.0102	0.0343
27	Mustard	0.0103	0.0343
28	Sweet_Pot_	0.0114	0.0366
29	Barley	0.0156	0.0483
30	Oat	0.0186	0.0558
31	Onion	0.0210	0.0609
32	Peach	0.0224	0.0631
33	Chocolate	0.0235	0.0640

<i>Rank</i>	<i>Food</i>	<i>Raw p-value</i>	<i>FDR Multiplicity-adj p-value</i>
34	Corn	0.0245	0.0649
35	Yogurt	0.0265	0.0682
36	Cola_Nut	0.0278	0.0694
37	Spinach	0.0312	0.0750
38	Safflower	0.0317	0.0750
39	Swiss_Ch_	0.0333	0.0768
40	Lima_Bean	0.0363	0.0817
41	Apple	0.0373	0.0820
42	Avocado	0.0398	0.0853
43	Strawberry	0.0456	0.0954
44	Oyster	0.0499	0.1021
45	Pinto_Bean	0.0540	0.1079
46	Celery	0.0584	0.1107
47	Honey	0.0590	0.1107
48	Walnut_Bl	0.0601	0.1107
49	Pineapple	0.0603	0.1107
50	Cabbage	0.0804	0.1439
51	Rice	0.0815	0.1439
52	Salmon	0.0904	0.1565
53	Eggplant	0.0976	0.1657
54	Tea	0.1083	0.1805
55	Peanut	0.1185	0.1920
56	Amer__Cheese	0.1198	0.1920
57	String_Bean	0.1216	0.1920
58	Trout	0.1495	0.2319
59	Goat_Milk	0.1634	0.2493
60	Cinnamon	0.1671	0.2506
61	Yeast_Baker	0.1731	0.2554
62	Yeast_Brewer	0.1858	0.2697
63	Soybean	0.2054	0.2934
64	Parsley	0.2130	0.2995
65	Lobster	0.2334	0.3232
66	Sardine	0.2382	0.3248
67	Squashes	0.2868	0.3831
68	Cashew	0.2895	0.3831
69	Shrimp	0.3348	0.4367
70	Beef	0.3748	0.4774

<i>Rank</i>	<i>Food</i>	<i>Raw p-value</i>	<i>FDR Multiplicity-adj p-value</i>
71	Sesame	0.3766	0.4774
72	Coffee	0.3870	0.4838
73	Crab	0.3927	0.4841
74	Halibut	0.4073	0.4922
75	Chicken	0.4102	0.4922
76	Scallop	0.4218	0.4995
77	Turkey	0.4446	0.5196
78	Mushroom	0.4977	0.5742
79	Lettuce	0.5049	0.5752
80	Clam	0.5689	0.6400
81	Banana	0.5968	0.6598
82	Olive	0.6036	0.6598
83	Chili_Pepper	0.6085	0.6598
84	Millet	0.7367	0.7823
85	Potato	0.7388	0.7823
86	Blueberry	0.7809	0.8172
87	Codfish	0.8882	0.9188
88	Pork	0.9271	0.9396
89	Sole	0.9292	0.9396
90	Tuna	0.9887	0.9887

Table 2

**Basic Descriptive Statistics of ELISA Score by Food and Gender
Comparing Fibromyalgia to Control**

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
FEMALE	Almond	Fibromyalgia	104	6.866	8.154	0.111	46.426
		Control	66	4.034	2.187	0.100	13.068
		Diff (1-2)	—	2.832	6.528	—	—
	Amer__Cheese	Fibromyalgia	104	32.894	54.212	0.100	400.00
		Control	66	23.434	52.616	0.100	400.00
		Diff (1-2)	—	9.460	53.600	—	—
	Apple	Fibromyalgia	104	6.778	13.068	0.100	114.43
		Control	66	4.432	3.291	0.100	15.890
		Diff (1-2)	—	2.345	10.435	—	—
	Avocado	Fibromyalgia	104	3.732	5.010	0.100	45.754
		Control	66	2.930	2.339	0.100	14.256
		Diff (1-2)	—	0.802	4.184	—	—
	Banana	Fibromyalgia	104	10.238	16.207	1.177	117.19
		Control	66	8.063	14.962	0.100	83.654
		Diff (1-2)	—	2.176	15.737	—	—
	Barley	Fibromyalgia	104	23.295	18.036	3.039	104.90
		Control	66	19.090	12.984	3.026	64.831
		Diff (1-2)	—	4.205	16.268	—	—
	Beef	Fibromyalgia	104	10.201	12.027	1.519	78.251
		Control	66	10.288	13.960	3.026	104.76
		Diff (1-2)	—	-0.087	12.809	—	—
	Blueberry	Fibromyalgia	104	5.123	5.670	0.100	51.308
		Control	66	5.440	3.773	0.100	26.772
		Diff (1-2)	—	-0.317	5.022	—	—
	Broccoli	Fibromyalgia	104	11.356	23.435	1.329	227.12
		Control	66	6.280	5.292	0.100	36.378
		Diff (1-2)	—	5.075	18.643	—	—
	Buck_Wheat	Fibromyalgia	104	10.005	8.601	0.893	43.056
		Control	66	8.034	4.990	1.316	29.397
		Diff (1-2)	—	1.970	7.415	—	—
	Butter	Fibromyalgia	104	28.848	32.166	0.100	198.50
		Control	66	21.874	29.162	0.100	204.33
		Diff (1-2)	—	6.975	31.038	—	—
	Cabbage	Fibromyalgia	104	12.579	32.893	0.685	314.52
		Control	66	7.362	10.123	0.100	56.932

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Diff (1-2)	—	5.217	26.514	—	—
	Cane_Sugar	Fibromyalgia	104	27.698	19.696	5.550	100.51
		Control	66	18.288	9.172	2.632	43.466
		Diff (1-2)	—	9.409	16.444	—	—
	Cantaloupe	Fibromyalgia	104	14.849	36.920	0.100	343.58
		Control	66	6.154	6.160	0.100	48.752
		Diff (1-2)	—	8.695	29.161	—	—
	Carrot	Fibromyalgia	104	7.589	9.322	0.100	47.604
		Control	66	4.813	3.705	0.100	24.141
		Diff (1-2)	—	2.776	7.654	—	—
	Cashew	Fibromyalgia	104	13.180	41.926	0.100	400.00
		Control	66	9.924	16.382	0.100	94.907
		Diff (1-2)	—	3.257	34.373	—	—
	Cauliflower	Fibromyalgia	104	11.767	34.512	0.100	333.15
		Control	66	5.977	8.336	0.100	58.808
		Diff (1-2)	—	5.789	27.516	—	—
	Celery	Fibromyalgia	104	10.965	10.116	1.116	55.571
		Control	66	9.634	5.975	0.395	32.141
		Diff (1-2)	—	1.331	8.750	—	—
	Cheddar_Ch_	Fibromyalgia	104	49.374	77.026	1.284	400.00
		Control	66	26.852	55.697	0.100	400.00
		Diff (1-2)	—	22.522	69.554	—	—
	Chicken	Fibromyalgia	104	20.771	25.257	4.181	198.87
		Control	66	18.303	10.514	4.743	61.887
		Diff (1-2)	—	2.468	20.830	—	—
	Chili_Pepper	Fibromyalgia	104	8.677	8.453	1.888	63.830
		Control	66	8.577	7.784	0.100	42.583
		Diff (1-2)	—	0.101	8.201	—	—
	Chocolate	Fibromyalgia	104	18.684	13.013	4.369	64.612
		Control	66	14.350	6.578	3.006	35.317
		Diff (1-2)	—	4.334	10.980	—	—
	Cinnamon	Fibromyalgia	104	39.601	42.191	6.818	400.00
		Control	66	32.170	24.180	5.374	132.49
		Diff (1-2)	—	7.432	36.298	—	—
	Clam	Fibromyalgia	104	39.460	44.688	7.415	386.76
		Control	66	52.166	58.253	7.819	400.00
		Diff (1-2)	—	-12.706	50.371	—	—

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
	Codfish	Fibromyalgia	104	25.773	36.083	4.069	332.12
		Control	66	29.652	31.720	6.200	168.28
		Diff (1-2)	—	-3.878	34.460	—	—
	Coffee	Fibromyalgia	104	23.872	45.280	1.709	400.00
		Control	66	29.631	46.880	5.215	346.81
		Diff (1-2)	—	-5.759	45.906	—	—
	Cola_Nut	Fibromyalgia	104	35.300	17.077	8.942	92.145
		Control	66	29.138	12.588	8.723	58.129
		Diff (1-2)	—	6.161	15.495	—	—
	Corn	Fibromyalgia	104	18.260	30.430	1.597	192.99
		Control	66	11.407	23.137	0.100	187.68
		Diff (1-2)	—	6.853	27.835	—	—
	Cottage_Ch_	Fibromyalgia	104	116.704	131.580	1.654	400.00
		Control	66	76.158	92.333	0.100	400.00
		Diff (1-2)	—	40.546	117.954	—	—
	Cow_Milk	Fibromyalgia	104	103.716	114.993	1.946	400.00
		Control	66	75.882	86.959	0.100	400.00
		Diff (1-2)	—	27.834	105.038	—	—
	Crab	Fibromyalgia	104	28.534	38.151	3.526	220.27
		Control	66	23.583	17.654	3.803	93.236
		Diff (1-2)	—	4.952	31.827	—	—
	Cucumber	Fibromyalgia	104	16.306	42.818	0.100	400.00
		Control	66	8.461	8.149	0.100	38.939
		Diff (1-2)	—	7.845	33.907	—	—
	Egg	Fibromyalgia	104	81.527	108.175	1.493	400.00
		Control	66	55.102	89.966	0.100	400.00
		Diff (1-2)	—	26.425	101.518	—	—
	Eggplant	Fibromyalgia	104	9.115	21.560	0.100	209.04
		Control	66	5.732	5.993	0.100	31.330
		Diff (1-2)	—	3.383	17.288	—	—
	Garlic	Fibromyalgia	104	17.556	14.416	3.914	81.000
		Control	66	11.174	5.779	3.380	28.482
		Diff (1-2)	—	6.382	11.846	—	—
	Goat_Milk	Fibromyalgia	104	24.272	47.547	0.223	400.00
		Control	66	15.413	28.452	0.100	180.08
		Diff (1-2)	—	8.859	41.222	—	—
	Grape	Fibromyalgia	104	17.935	15.350	6.103	148.70

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Control	66	20.276	6.827	10.650	47.817
		Diff (1-2)	—	-2.341	12.747	—	—
	Grapefruit	Fibromyalgia	104	4.700	6.472	0.100	44.776
		Control	66	3.278	2.446	0.100	14.364
		Diff (1-2)	—	1.422	5.291	—	—
	Green_Pea	Fibromyalgia	104	16.209	19.161	1.200	115.38
		Control	66	8.631	7.160	0.496	32.502
		Diff (1-2)	—	7.578	15.650	—	—
	Green_Pepper	Fibromyalgia	104	7.263	12.434	0.558	106.15
		Control	66	4.149	2.875	0.100	14.364
		Diff (1-2)	—	3.114	9.899	—	—
	Halibut	Fibromyalgia	104	10.871	8.183	2.825	60.396
		Control	66	11.119	7.129	2.729	44.884
		Diff (1-2)	—	-0.248	7.793	—	—
	Honey	Fibromyalgia	104	12.115	7.131	3.698	44.883
		Control	66	10.185	4.203	4.227	19.876
		Diff (1-2)	—	1.930	6.165	—	—
	Lemon	Fibromyalgia	104	3.057	2.538	0.100	14.799
		Control	66	2.482	2.159	0.100	14.688
		Diff (1-2)	—	0.575	2.398	—	—
	Lettuce	Fibromyalgia	104	12.314	12.925	2.096	91.898
		Control	66	11.368	6.472	0.921	29.851
		Diff (1-2)	—	0.945	10.892	—	—
	Lima_Bean	Fibromyalgia	104	8.931	12.353	0.100	91.262
		Control	66	6.624	8.761	0.100	65.634
		Diff (1-2)	—	2.307	11.102	—	—
	Lobster	Fibromyalgia	104	13.222	10.990	2.416	67.512
		Control	66	13.398	8.359	3.938	46.560
		Diff (1-2)	—	-0.176	10.054	—	—
	Malt	Fibromyalgia	104	29.021	19.023	5.035	120.44
		Control	66	21.743	11.326	3.684	57.151
		Diff (1-2)	—	7.278	16.477	—	—
	Millet	Fibromyalgia	104	4.533	4.406	0.100	38.706
		Control	66	4.889	7.091	0.100	46.663
		Diff (1-2)	—	-0.355	5.599	—	—
	Mushroom	Fibromyalgia	104	11.987	16.126	0.781	106.30
		Control	66	13.174	12.549	1.117	49.656

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Diff (1-2)	—	-1.186	14.845	—	—
	Mustard	Fibromyalgia	104	12.829	16.641	1.814	138.71
		Control	66	8.842	5.224	0.100	23.452
		Diff (1-2)	—	3.986	13.429	—	—
	Oat	Fibromyalgia	104	31.653	53.336	2.486	400.00
		Control	66	16.237	14.506	0.100	76.165
		Diff (1-2)	—	15.416	42.726	—	—
	Olive	Fibromyalgia	104	26.127	25.998	4.096	154.59
		Control	66	23.704	14.281	5.272	59.488
		Diff (1-2)	—	2.423	22.211	—	—
	Onion	Fibromyalgia	104	20.777	47.044	1.168	400.00
		Control	66	11.329	16.935	1.184	114.37
		Diff (1-2)	—	9.448	38.312	—	—
	Orange	Fibromyalgia	104	23.272	23.716	2.531	137.93
		Control	66	15.289	11.608	1.489	47.125
		Diff (1-2)	—	7.983	19.924	—	—
	Oyster	Fibromyalgia	104	51.045	60.373	5.679	400.00
		Control	66	42.674	33.485	5.656	168.59
		Diff (1-2)	—	8.371	51.658	—	—
	Parsley	Fibromyalgia	104	7.299	16.418	0.100	110.20
		Control	66	5.005	6.541	0.100	34.932
		Diff (1-2)	—	2.294	13.484	—	—
	Peach	Fibromyalgia	104	12.707	22.074	0.100	177.51
		Control	66	7.145	7.742	0.100	33.820
		Diff (1-2)	—	5.562	17.943	—	—
	Peanut	Fibromyalgia	104	5.527	6.125	0.100	35.339
		Control	66	5.563	4.941	0.100	26.567
		Diff (1-2)	—	-0.036	5.696	—	—
	Pineapple	Fibromyalgia	104	35.809	46.427	1.684	334.56
		Control	66	23.710	46.114	0.100	278.44
		Diff (1-2)	—	12.099	46.307	—	—
	Pinto_Bean	Fibromyalgia	104	11.544	13.984	1.451	92.587
		Control	66	10.138	8.167	0.100	48.623
		Diff (1-2)	—	1.406	12.071	—	—
	Pork	Fibromyalgia	104	15.811	35.635	2.700	361.65
		Control	66	15.347	10.345	4.339	65.759
		Diff (1-2)	—	0.464	28.634	—	—

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
	Potato	Fibromyalgia	104	13.853	12.948	3.729	94.518
		Control	66	13.615	6.063	6.200	40.802
		Diff (1-2)	—	0.238	10.817	—	—
	Rice	Fibromyalgia	104	28.346	20.223	4.559	121.63
		Control	66	21.551	16.950	3.350	92.642
		Diff (1-2)	—	6.795	19.024	—	—
	Rye	Fibromyalgia	104	7.150	5.434	1.855	33.862
		Control	66	5.237	3.633	0.100	22.824
		Diff (1-2)	—	1.913	4.817	—	—
	Safflower	Fibromyalgia	104	11.982	15.146	1.890	100.00
		Control	66	8.776	8.189	1.722	48.833
		Diff (1-2)	—	3.206	12.907	—	—
	Salmon	Fibromyalgia	104	8.186	6.142	1.890	35.269
		Control	66	9.377	7.261	2.862	56.530
		Diff (1-2)	—	-1.191	6.597	—	—
	Sardine	Fibromyalgia	104	39.069	20.513	10.415	119.47
		Control	66	37.084	16.695	7.190	88.964
		Diff (1-2)	—	1.985	19.126	—	—
	Scallop	Fibromyalgia	104	59.222	42.535	16.297	343.67
		Control	66	64.291	29.551	18.605	148.58
		Diff (1-2)	—	-5.069	38.041	—	—
	Sesame	Fibromyalgia	104	53.877	75.747	1.810	400.00
		Control	66	80.704	93.902	5.984	400.00
		Diff (1-2)	—	-26.827	83.242	—	—
	Shrimp	Fibromyalgia	104	21.275	22.260	4.746	140.12
		Control	66	33.150	27.875	6.607	113.66
		Diff (1-2)	—	-11.875	24.585	—	—
	Sole	Fibromyalgia	104	5.326	2.997	1.259	22.181
		Control	66	6.440	6.960	0.100	54.883
		Diff (1-2)	—	-1.114	4.924	—	—
	Soybean	Fibromyalgia	104	17.526	25.299	2.232	218.84
		Control	66	15.294	9.373	2.481	49.071
		Diff (1-2)	—	2.232	20.649	—	—
	Spinach	Fibromyalgia	104	24.568	42.259	4.407	400.00
		Control	66	20.485	13.172	6.051	66.626
		Diff (1-2)	—	4.083	34.088	—	—
	Squashes	Fibromyalgia	104	14.294	11.270	3.324	92.054

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Control	66	13.415	11.597	1.842	74.279
		Diff (1-2)	—	0.879	11.398	—	—
	Strawberry	Fibromyalgia	104	9.001	22.283	0.100	185.25
		Control	66	5.563	5.305	0.100	35.745
		Diff (1-2)	—	3.439	17.757	—	—
	String_Bean	Fibromyalgia	104	46.993	37.664	11.415	310.37
		Control	66	41.957	22.678	9.539	125.69
		Diff (1-2)	—	5.036	32.691	—	—
	Sunflower_Sd	Fibromyalgia	104	13.241	15.579	3.092	112.94
		Control	66	9.948	6.094	2.632	33.347
		Diff (1-2)	—	3.293	12.774	—	—
	Sweet_Pot_	Fibromyalgia	104	13.890	28.677	0.111	277.70
		Control	66	8.592	4.479	0.395	25.009
		Diff (1-2)	—	5.297	22.626	—	—
	Swiss_Ch_	Fibromyalgia	104	66.212	102.077	0.949	400.00
		Control	66	39.219	73.725	0.100	400.00
		Diff (1-2)	—	26.992	92.148	—	—
	Tea	Fibromyalgia	104	34.435	25.311	10.453	205.69
		Control	66	29.771	12.014	11.634	64.535
		Diff (1-2)	—	4.664	21.181	—	—
	Tobacco	Fibromyalgia	104	48.892	36.337	6.653	195.17
		Control	66	33.566	16.789	7.809	82.097
		Diff (1-2)	—	15.326	30.308	—	—
	Tomato	Fibromyalgia	104	19.611	43.308	1.866	400.00
		Control	66	9.066	7.694	0.100	42.078
		Diff (1-2)	—	10.545	34.246	—	—
	Trout	Fibromyalgia	104	13.998	9.182	3.949	45.736
		Control	66	16.138	10.667	5.596	76.221
		Diff (1-2)	—	-2.139	9.783	—	—
	Tuna	Fibromyalgia	104	13.827	8.789	4.077	45.795
		Control	66	18.092	12.707	3.873	64.090
		Diff (1-2)	—	-4.265	10.480	—	—
	Turkey	Fibromyalgia	104	17.087	24.758	2.567	220.43
		Control	66	14.461	6.976	4.094	32.151
		Diff (1-2)	—	2.626	19.865	—	—
	Walnut_Blk	Fibromyalgia	104	32.446	38.371	7.383	330.22
		Control	66	25.386	17.254	6.943	117.46

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
MALE	Wheat	Diff (1-2)	—	7.060	31.904	—	—
		Fibromyalgia	104	23.569	22.292	3.773	136.82
		Control	66	18.402	29.364	0.790	209.95
	Yeast_Baker	Diff (1-2)	—	5.167	25.264	—	—
		Fibromyalgia	104	10.241	14.391	0.100	101.86
		Control	66	5.545	3.349	0.526	18.811
	Yeast_Brewer	Diff (1-2)	—	4.696	11.459	—	—
		Fibromyalgia	104	23.961	37.525	1.866	261.68
		Control	66	10.847	7.818	0.100	43.887
	Yogurt	Diff (1-2)	—	13.114	29.782	—	—
		Fibromyalgia	104	30.777	45.989	0.558	400.00
		Control	66	22.930	30.973	0.100	215.73
	Almond	Diff (1-2)	—	7.848	40.839	—	—
		Fibromyalgia	16	6.539	6.465	1.849	27.955
		Control	97	4.049	2.231	0.100	12.591
	Amer__Cheese	Diff (1-2)	—	2.490	3.155	—	—
		Fibromyalgia	16	27.415	43.656	4.791	187.82
		Control	97	22.619	34.069	0.468	197.38
	Apple	Diff (1-2)	—	4.796	35.516	—	—
		Fibromyalgia	16	6.385	10.738	1.768	46.209
		Control	97	4.383	2.900	0.100	13.795
	Avocado	Diff (1-2)	—	2.002	4.781	—	—
		Fibromyalgia	16	4.812	6.891	1.522	29.968
		Control	97	2.720	2.992	0.100	28.693
	Banana	Diff (1-2)	—	2.092	3.763	—	—
		Fibromyalgia	16	10.330	10.714	1.562	39.781
		Control	97	8.576	36.151	0.100	350.69
	Barley	Diff (1-2)	—	1.753	33.850	—	—
		Fibromyalgia	16	25.904	12.798	9.629	46.261
		Control	97	19.214	11.923	4.612	58.865
	Beef	Diff (1-2)	—	6.690	12.045	—	—
		Fibromyalgia	16	19.177	34.495	3.228	145.97
		Control	97	9.327	11.981	2.059	93.494
	Blueberry	Diff (1-2)	—	9.850	16.880	—	—
		Fibromyalgia	16	6.000	5.801	2.145	23.321
		Control	97	5.393	2.868	0.100	19.410
		Diff (1-2)	—	0.606	3.415	—	—

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
	Broccoli	Fibromyalgia	16	8.863	10.627	2.156	47.207
		Control	97	6.790	8.012	0.131	72.543
		Diff (1-2)	—	2.073	8.413	—	—
	Buck_Wheat	Fibromyalgia	16	7.854	4.881	3.541	23.112
		Control	97	6.978	3.384	2.656	24.338
		Diff (1-2)	—	0.876	3.622	—	—
	Butter	Fibromyalgia	16	26.841	20.680	5.312	89.665
		Control	97	17.846	20.091	1.490	131.60
		Diff (1-2)	—	8.996	20.172	—	—
	Cabbage	Fibromyalgia	16	8.728	11.722	1.437	49.551
		Control	97	6.540	18.133	0.100	174.96
		Diff (1-2)	—	2.187	17.405	—	—
	Cane_Sugar	Fibromyalgia	16	25.887	15.259	10.013	68.752
		Control	97	22.356	18.718	2.789	100.82
		Diff (1-2)	—	3.532	18.289	—	—
	Cantaloupe	Fibromyalgia	16	12.556	14.175	2.259	50.674
		Control	97	6.052	5.569	0.468	38.706
		Diff (1-2)	—	6.504	7.347	—	—
	Carrot	Fibromyalgia	16	8.221	12.434	1.963	40.198
		Control	97	4.684	3.636	0.468	28.593
		Diff (1-2)	—	3.537	5.686	—	—
	Cashew	Fibromyalgia	16	14.183	14.699	1.631	56.453
		Control	97	8.362	10.271	0.100	55.749
		Diff (1-2)	—	5.821	10.974	—	—
	Cauliflower	Fibromyalgia	16	7.822	13.577	1.770	58.086
		Control	97	4.385	4.396	0.100	36.593
		Diff (1-2)	—	3.437	6.452	—	—
	Celery	Fibromyalgia	16	13.059	13.953	3.927	61.457
		Control	97	8.930	4.985	2.394	26.982
		Diff (1-2)	—	4.129	6.913	—	—
	Cheddar_Ch_	Fibromyalgia	16	49.218	95.326	1.874	400.00
		Control	97	28.479	49.022	1.169	298.91
		Diff (1-2)	—	20.739	57.501	—	—
	Chicken	Fibromyalgia	16	14.927	7.518	5.865	31.125
		Control	97	17.778	11.456	5.137	69.503
		Diff (1-2)	—	-2.851	11.006	—	—
	Chili_Pepper	Fibromyalgia	16	8.041	6.014	3.141	27.850

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Control	97	7.802	5.945	1.591	31.070
		Diff (1-2)	—	0.239	5.954	—	—
	Chocolate	Fibromyalgia	16	20.082	13.777	5.755	61.471
		Control	97	16.536	11.276	1.726	63.673
		Diff (1-2)	—	3.546	11.645	—	—
	Cinnamon	Fibromyalgia	16	45.368	28.876	4.416	116.98
		Control	97	35.928	28.520	3.136	146.95
		Diff (1-2)	—	9.440	28.568	—	—
	Clam	Fibromyalgia	16	50.302	30.299	17.444	145.47
		Control	97	38.293	21.598	6.370	103.47
		Diff (1-2)	—	12.009	22.968	—	—
	Codfish	Fibromyalgia	16	18.752	6.773	7.252	30.303
		Control	97	22.538	29.644	4.176	269.16
		Diff (1-2)	—	-3.786	27.680	—	—
	Coffee	Fibromyalgia	16	63.423	98.125	3.456	332.65
		Control	97	20.037	24.002	2.705	192.24
		Diff (1-2)	—	43.386	42.419	—	—
	Cola_Nut	Fibromyalgia	16	40.763	19.064	15.113	75.518
		Control	97	32.919	20.025	3.851	112.10
		Diff (1-2)	—	7.844	19.898	—	—
	Corn	Fibromyalgia	16	11.506	10.211	3.389	35.845
		Control	97	10.126	15.048	1.520	117.90
		Diff (1-2)	—	1.381	14.489	—	—
	Cottage_Ch_	Fibromyalgia	16	116.031	93.106	3.332	400.00
		Control	97	74.814	101.386	1.446	400.00
		Diff (1-2)	—	41.217	100.307	—	—
	Cow_Milk	Fibromyalgia	16	110.736	90.643	3.645	400.00
		Control	97	68.606	94.032	1.343	400.00
		Diff (1-2)	—	42.131	93.581	—	—
	Crab	Fibromyalgia	16	20.897	10.756	6.163	43.612
		Control	97	24.550	29.311	3.108	252.41
		Diff (1-2)	—	-3.653	27.544	—	—
	Cucumber	Fibromyalgia	16	20.634	38.899	2.395	148.77
		Control	97	8.320	9.298	0.234	69.188
		Diff (1-2)	—	12.314	16.711	—	—
	Egg	Fibromyalgia	16	82.523	91.370	2.434	307.44
		Control	97	44.335	66.828	0.100	400.00

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Diff (1-2)	—	38.188	70.644	—	—
	Eggplant	Fibromyalgia	16	8.510	13.094	1.907	55.212
		Control	97	5.856	10.455	0.100	92.376
		Diff (1-2)	—	2.654	10.849	—	—
	Garlic	Fibromyalgia	16	18.802	21.978	4.614	81.120
		Control	97	13.476	12.122	3.097	70.591
		Diff (1-2)	—	5.327	13.870	—	—
	Goat_Milk	Fibromyalgia	16	22.036	33.196	2.082	139.40
		Control	97	17.999	36.202	0.100	275.19
		Diff (1-2)	—	4.037	35.810	—	—
	Grape	Fibromyalgia	16	19.689	14.273	9.280	68.874
		Control	97	23.308	7.422	11.900	41.654
		Diff (1-2)	—	-3.619	8.670	—	—
	Grapefruit	Fibromyalgia	16	6.572	10.236	0.833	40.716
		Control	97	3.049	2.306	0.100	14.648
		Diff (1-2)	—	3.523	4.331	—	—
	Green_Pea	Fibromyalgia	16	11.105	8.005	2.542	26.055
		Control	97	9.229	11.366	0.100	71.765
		Diff (1-2)	—	1.876	10.972	—	—
	Green_Pepper	Fibromyalgia	16	8.192	11.462	1.992	45.655
		Control	97	3.972	2.664	0.100	15.744
		Diff (1-2)	—	4.220	4.888	—	—
	Halibut	Fibromyalgia	16	11.297	6.460	4.869	28.933
		Control	97	12.657	15.451	0.818	142.09
		Diff (1-2)	—	-1.360	14.564	—	—
	Honey	Fibromyalgia	16	12.916	8.637	4.886	32.594
		Control	97	11.082	6.215	2.434	31.202
		Diff (1-2)	—	1.833	6.595	—	—
	Lemon	Fibromyalgia	16	4.552	5.861	1.191	23.846
		Control	97	2.310	1.436	0.100	8.383
		Diff (1-2)	—	2.242	2.535	—	—
	Lettuce	Fibromyalgia	16	11.305	8.401	4.409	33.615
		Control	97	11.271	8.295	2.871	52.209
		Diff (1-2)	—	0.034	8.309	—	—
	Lima_Bean	Fibromyalgia	16	7.734	6.990	2.258	29.544
		Control	97	5.994	5.650	0.100	37.640
		Diff (1-2)	—	1.740	5.849	—	—

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
	Lobster	Fibromyalgia	16	13.151	10.097	3.697	40.844
		Control	97	15.678	11.555	0.468	61.064
		Diff (1-2)	—	-2.527	11.369	—	—
	Malt	Fibromyalgia	16	24.439	11.769	10.005	57.099
		Control	97	21.137	12.373	3.182	58.638
		Diff (1-2)	—	3.302	12.293	—	—
	Millet	Fibromyalgia	16	5.071	3.834	1.770	16.847
		Control	97	4.006	6.783	0.100	67.831
		Diff (1-2)	—	1.065	6.463	—	—
	Mushroom	Fibromyalgia	16	10.708	9.141	2.766	38.180
		Control	97	12.883	12.397	1.350	59.949
		Diff (1-2)	—	-2.174	12.009	—	—
	Mustard	Fibromyalgia	16	11.298	8.894	2.670	31.990
		Control	97	9.168	5.413	1.044	28.538
		Diff (1-2)	—	2.130	6.003	—	—
	Oat	Fibromyalgia	16	19.952	19.358	3.286	71.326
		Control	97	20.964	22.946	1.461	107.25
		Diff (1-2)	—	-1.012	22.495	—	—
	Olive	Fibromyalgia	16	23.759	19.540	8.224	77.477
		Control	97	24.794	22.708	5.137	160.63
		Diff (1-2)	—	-1.035	22.306	—	—
	Onion	Fibromyalgia	16	35.524	85.611	2.499	340.29
		Control	97	11.600	17.551	1.175	158.57
		Diff (1-2)	—	23.924	35.452	—	—
	Orange	Fibromyalgia	16	45.485	49.783	4.980	142.14
		Control	97	17.767	16.361	2.146	79.419
		Diff (1-2)	—	27.719	23.800	—	—
	Oyster	Fibromyalgia	16	83.648	73.071	5.194	226.37
		Control	97	43.016	35.689	5.069	216.58
		Diff (1-2)	—	40.631	42.698	—	—
	Parsley	Fibromyalgia	16	3.926	4.567	0.953	18.516
		Control	97	4.867	7.352	0.100	58.674
		Diff (1-2)	—	-0.942	7.040	—	—
	Peach	Fibromyalgia	16	11.021	19.050	1.767	80.723
		Control	97	8.390	8.373	0.100	50.444
		Diff (1-2)	—	2.631	10.473	—	—
	Peanut	Fibromyalgia	16	8.482	10.553	1.438	40.511

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Control	97	4.241	4.514	0.855	41.070
		Diff (1-2)	—	4.241	5.716	—	—
	Pineapple	Fibromyalgia	16	20.060	17.114	2.156	54.139
		Control	97	23.259	48.769	0.100	400.00
		Diff (1-2)	—	-3.199	45.789	—	—
	Pinto_Bean	Fibromyalgia	16	11.702	11.082	3.480	45.766
		Control	97	8.132	5.524	0.664	28.288
		Diff (1-2)	—	3.570	6.556	—	—
	Pork	Fibromyalgia	16	9.812	6.200	4.211	27.216
		Control	97	13.403	10.218	1.637	57.274
		Diff (1-2)	—	-3.591	9.772	—	—
	Potato	Fibromyalgia	16	13.007	12.697	6.630	58.433
		Control	97	14.555	5.951	5.259	49.002
		Diff (1-2)	—	-1.548	7.240	—	—
	Rice	Fibromyalgia	16	23.602	12.743	6.471	49.103
		Control	97	25.220	18.948	5.149	118.12
		Diff (1-2)	—	-1.618	18.233	—	—
	Rye	Fibromyalgia	16	6.439	5.695	2.656	25.318
		Control	97	4.801	2.690	0.653	15.288
		Diff (1-2)	—	1.638	3.262	—	—
	Safflower	Fibromyalgia	16	10.340	9.028	4.270	41.479
		Control	97	8.672	6.177	1.958	38.914
		Diff (1-2)	—	1.668	6.634	—	—
	Salmon	Fibromyalgia	16	10.727	7.974	3.471	35.394
		Control	97	10.920	13.350	0.100	125.74
		Diff (1-2)	—	-0.194	12.756	—	—
	Sardine	Fibromyalgia	16	43.811	17.154	13.774	77.602
		Control	97	37.035	15.979	7.037	90.406
		Diff (1-2)	—	6.775	16.142	—	—
	Scallop	Fibromyalgia	16	54.453	20.844	21.408	89.162
		Control	97	60.721	32.618	8.942	167.75
		Diff (1-2)	—	-6.268	31.287	—	—
	Sesame	Fibromyalgia	16	96.289	146.039	3.694	400.00
		Control	97	60.406	79.861	2.115	400.00
		Diff (1-2)	—	35.883	91.640	—	—
	Shrimp	Fibromyalgia	16	26.078	25.220	6.208	110.09
		Control	97	34.490	42.689	2.663	342.67

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
		Diff (1-2)	—	-8.412	40.768	—	—
	Sole	Fibromyalgia	16	6.501	4.160	3.081	18.195
		Control	97	4.912	2.238	0.100	14.303
		Diff (1-2)	—	1.588	2.583	—	—
	Soybean	Fibromyalgia	16	28.910	36.666	5.865	151.84
		Control	97	15.880	9.273	4.912	71.264
		Diff (1-2)	—	13.030	16.002	—	—
	Spinach	Fibromyalgia	16	20.374	13.020	5.865	56.587
		Control	97	14.656	7.304	3.054	39.867
		Diff (1-2)	—	5.718	8.310	—	—
	Squashes	Fibromyalgia	16	14.433	6.654	5.891	28.769
		Control	97	12.688	7.539	1.637	49.775
		Diff (1-2)	—	1.745	7.426	—	—
	Strawberry	Fibromyalgia	16	7.037	10.351	1.547	44.110
		Control	97	4.767	4.446	0.100	30.664
		Diff (1-2)	—	2.270	5.619	—	—
	String_Bean	Fibromyalgia	16	47.501	24.375	14.907	110.20
		Control	97	40.720	22.088	5.609	141.76
		Diff (1-2)	—	6.781	22.411	—	—
	Sunflower_Sd	Fibromyalgia	16	13.339	11.669	4.886	53.027
		Control	97	9.071	5.842	2.523	46.948
		Diff (1-2)	—	4.268	6.922	—	—
	Sweet_Pot_	Fibromyalgia	16	11.130	13.605	3.829	59.941
		Control	97	8.456	4.878	0.100	30.052
		Diff (1-2)	—	2.673	6.752	—	—
	Swiss_Ch_	Fibromyalgia	16	58.705	95.086	2.499	400.00
		Control	97	43.413	79.791	0.100	400.00
		Diff (1-2)	—	15.292	82.025	—	—
	Tea	Fibromyalgia	16	36.294	18.765	16.659	92.933
		Control	97	31.353	13.716	8.890	70.271
		Diff (1-2)	—	4.941	14.501	—	—
	Tobacco	Fibromyalgia	16	43.760	23.040	18.248	111.50
		Control	97	39.354	26.787	6.106	134.30
		Diff (1-2)	—	4.406	26.312	—	—
	Tomato	Fibromyalgia	16	13.506	24.683	2.873	104.91
		Control	97	9.088	7.957	0.100	48.338
		Diff (1-2)	—	4.418	11.708	—	—

Sex	Food	Diagnosis	N	ELISA Score			
				Mean	SD	Min	Max
	Trout	Fibromyalgia	16	17.896	14.935	5.787	52.661
		Control	97	16.891	15.673	0.100	144.46
		Diff (1-2)	—	1.005	15.575	—	—
	Tuna	Fibromyalgia	16	18.349	7.321	6.006	28.898
		Control	97	18.392	16.755	3.156	110.69
		Diff (1-2)	—	-0.043	15.812	—	—
	Turkey	Fibromyalgia	16	13.357	7.658	4.316	31.819
		Control	97	14.840	10.829	2.789	69.572
		Diff (1-2)	—	-1.483	10.457	—	—
	Walnut_Blk	Fibromyalgia	16	28.937	16.976	7.396	60.274
		Control	97	25.520	14.492	4.249	71.927
		Diff (1-2)	—	3.416	14.852	—	—
	Wheat	Fibromyalgia	16	24.605	40.778	4.905	172.41
		Control	97	14.494	12.413	2.741	90.037
		Diff (1-2)	—	10.111	18.920	—	—
	Yeast_Baker	Fibromyalgia	16	10.665	12.878	1.770	52.149
		Control	97	9.617	17.250	1.305	116.43
		Diff (1-2)	—	1.047	16.726	—	—
	Yeast_Brewer	Fibromyalgia	16	23.797	37.480	2.264	150.60
		Control	97	22.646	47.630	1.931	308.34
		Diff (1-2)	—	1.152	46.389	—	—
	Yogurt	Fibromyalgia	16	28.000	30.574	4.791	136.57
		Control	97	19.210	20.751	0.234	120.51
		Diff (1-2)	—	8.790	22.332	—	—

Table 3

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

Top 43 Foods Ranked by Descending order of Discriminatory Ability using Permutation Test

<i>Food Ranking</i>	<i>Food</i>	<i>Sex</i>	<i>Cutpoint</i>	
			<i>90th percentile</i>	<i>95th percentile</i>
1	Almond	FEMALE	6.806	8.281
		MALE	7.249	8.795
2	Rye	FEMALE	8.531	12.411
		MALE	8.377	10.716
3	Cantaloupe	FEMALE	9.631	13.622
		MALE	11.335	16.195
4	Malt	FEMALE	36.665	41.840
		MALE	39.383	46.273
5	Green_Pea	FEMALE	20.779	23.752
		MALE	20.065	32.972
6	Green_Pepper	FEMALE	8.334	10.403
		MALE	7.005	9.750
7	Tomato	FEMALE	17.703	23.769
		MALE	18.816	26.479
8	Orange	FEMALE	33.742	40.776
		MALE	37.416	57.433
9	Cane_Sugar	FEMALE	29.929	36.272
		MALE	46.054	66.208
10	Garlic	FEMALE	19.275	22.771
		MALE	27.791	42.223
11	Carrot	FEMALE	9.289	11.567
		MALE	7.810	10.821
12	Tobacco	FEMALE	57.672	64.333
		MALE	74.095	103.22
13	Cottage_Ch_	FEMALE	200.87	290.14
		MALE	223.76	354.07
14	Egg	FEMALE	145.73	285.66
		MALE	107.98	197.64
15	Buck_Wheat	FEMALE	14.800	18.567
		MALE	11.357	12.790
16	Grapefruit	FEMALE	6.254	7.715
		MALE	5.343	7.791
17	Cauliflower	FEMALE	11.707	18.003

<i>Food Ranking</i>	<i>Food</i>	<i>Sex</i>	<i>Cutpoint</i>	
			<i>90th percentile</i>	<i>95th percentile</i>
18	Lemon	MALE	8.032	11.278
		FEMALE	4.593	6.024
19	Grape	MALE	4.174	5.236
		FEMALE	26.963	32.236
20	Wheat	MALE	34.518	36.988
		FEMALE	30.681	59.893
21	Butter	MALE	27.344	37.916
		FEMALE	47.629	72.612
22	Sunflower_Sd	MALE	44.188	58.547
		FEMALE	16.583	22.695
23	Cow_Milk	MALE	14.267	18.717
		FEMALE	200.01	251.60
24	Cheddar_Ch_	MALE	184.93	321.92
		FEMALE	73.235	115.61
25	Broccoli	MALE	81.403	125.58
		FEMALE	11.932	15.004
26	Cucumber	MALE	13.219	16.352
		FEMALE	20.871	26.764
27	Mustard	MALE	17.798	24.104
		FEMALE	17.495	19.418
28	Sweet_Pot_	MALE	16.206	21.037
		FEMALE	14.609	17.450
29	Barley	MALE	13.858	18.249
		FEMALE	34.828	46.738
30	Oat	MALE	36.065	46.044
		FEMALE	33.192	44.637
31	Onion	MALE	56.146	74.118
		FEMALE	20.384	36.722
32	Peach	MALE	25.524	33.801
		FEMALE	18.354	27.039
33	Chocolate	MALE	17.862	26.746
		FEMALE	23.525	25.849
34	Corn	MALE	32.635	38.067
		FEMALE	19.718	31.687
35	Yogurt	MALE	19.888	29.679
		FEMALE	45.514	66.818

<i>Food Ranking</i>	<i>Food</i>	<i>Sex</i>	<i>Cutpoint</i>	
			<i>90th percentile</i>	<i>95th percentile</i>
36	Cola_Nut	MALE	43.693	66.879
		FEMALE	48.225	53.390
37	Spinach	MALE	59.945	73.033
		FEMALE	37.939	48.207
38	Safflower	MALE	24.952	28.642
		FEMALE	16.071	25.071
39	Swiss_Ch_	MALE	16.405	21.556
		FEMALE	104.27	198.10
40	Lima_Bean	MALE	112.62	226.17
		FEMALE	12.476	18.506
41	Apple	MALE	10.739	14.968
		FEMALE	9.055	11.927
42	Avocado	MALE	8.642	10.671
		FEMALE	5.440	7.385
43	Strawberry	MALE	4.469	5.671
		FEMALE	10.379	15.048
		MALE	8.947	13.865

Table 4

WO 2017/160869

PCT/US2017/022349

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
KH16-15897	4
KH16-16354	4
160905AAB0002	12
160905AAB0011	0
160905AAB0015	2
160905AAB0023	1
160905AAB0047	1
160905AAB0057	13
160905AAB0060	11
160905AAB0067	3
160905AAB0072	3
160905AAB0078	0
160905AAB0085	1
160905AAB0088	35
160905AAB0099	16
160905AAB0101	3
DLS15-15734	8
DLS15-18575	11
DLS16-31888	0
DLS16-32092	1
KH16-14191	0
KH16-14192	0
KH16-14193	6
KH16-15444	7
KH16-15445	0
KH16-15446	15
KH16-15894	2
KH16-15895	8
KH16-15896	2
KH16-16349	25
KH16-16350	17
KH16-16351	11
KH16-16352	1
KH16-16353	34
160905AAB0001	0
160905AAB0003	11
160905AAB0004	9
160905AAB0005	10
160905AAB0006	8
160905AAB0007	15
160905AAB0008	2
160905AAB0009	0

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1244900	2
BRH1244901	15
BRH1244902	1
BRH1244903	0
BRH1244904	1
BRH1244905	1
BRH1244906	15
BRH1244907	0
BRH1244908	3
BRH1244909	4
BRH1244910	7
BRH1244911	0
BRH1244912	1
BRH1244913	1
BRH1244914	9
BRH1244915	0
BRH1244916	6
BRH1244917	21
BRH1244918	6
BRH1244919	0
BRH1244920	3
BRH1244921	3
BRH1244922	25
BRH1244923	1
BRH1244924	0
BRH1244925	4
BRH1244926	17
BRH1244927	1
BRH1244928	6
BRH1244929	5
BRH1244930	0
BRH1244931	0
BRH1244932	11
BRH1244933	6
BRH1244934	10
BRH1244935	19
BRH1244936	0
BRH1244937	5
BRH1244938	8
BRH1244939	4
BRH1244940	1
BRH1244941	0

WO 2017/160869

PCT/US2017/022349

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
160905AAB0010	4
160905AAB0012	4
160905AAB0013	9
160905AAB0016	4
160905AAB0017	6
160905AAB0018	12
160905AAB0019	1
160905AAB0020	1
160905AAB0021	2
160905AAB0022	6
160905AAB0024	36
160905AAB0025	0
160905AAB0026	4
160905AAB0028	7
160905AAB0029	14
160905AAB0030	0
160905AAB0031	10
160905AAB0032	0
160905AAB0033	15
160905AAB0034	3
160905AAB0035	31
160905AAB0036	0
160905AAB0038	3
160905AAB0039	1
160905AAB0040	5
160905AAB0041	2
160905AAB0042	3
160905AAB0043	21
160905AAB0044	1
160905AAB0045	0
160905AAB0046	11
160905AAB0048	15
160905AAB0049	12
160905AAB0050	1
160905AAB0051	7
160905AAB0052	1
160905AAB0053	4
160905AAB0054	2
160905AAB0055	5
160905AAB0056	8
160905AAB0058	37
160905AAB0059	8

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1244942	10
BRH1244943	2
BRH1244944	29
BRH1244945	0
BRH1244946	12
BRH1244947	7
BRH1244948	3
BRH1244949	3
BRH1244950	2
BRH1244951	0
BRH1244952	1
BRH1244953	5
BRH1244954	0
BRH1244955	0
BRH1244956	35
BRH1244957	1
BRH1244958	3
BRH1244959	0
BRH1244960	0
BRH1244961	1
BRH1244962	2
BRH1244963	7
BRH1244964	7
BRH1244965	1
BRH1244966	2
BRH1244967	2
BRH1244968	2
BRH1244969	3
BRH1244970	6
BRH1244971	12
BRH1244972	0
BRH1244973	3
BRH1244974	1
BRH1244975	0
BRH1244976	1
BRH1244977	0
BRH1244978	0
BRH1244979	0
BRH1244980	0
BRH1244981	1
BRH1244982	0
BRH1244983	2

WO 2017/160869

PCT/US2017/022349

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
160905AAB0061	0
160905AAB0062	4
160905AAB0063	0
160905AAB0064	1
160905AAB0065	2
160905AAB0066	5
160905AAB0068	30
160905AAB0069	6
160905AAB0070	14
160905AAB0071	33
160905AAB0073	1
160905AAB0074	27
160905AAB0075	28
160905AAB0076	2
160905AAB0077	6
160905AAB0079	1
160905AAB0080	2
160905AAB0081	13
160905AAB0082	1
160905AAB0083	33
160905AAB0084	32
160905AAB0086	0
160905AAB0087	11
160905AAB0089	8
160905AAB0090	12
160905AAB0091	2
160905AAB0092	14
160905AAB0093	10
160905AAB0094	1
160905AAB0095	1
160905AAB0096	0
160905AAB0097	1
160905AAB0098	3
160905AAB0100	0
160905AAB0102	31
160905AAB0103	27

No of Observations	120
Average Number	8.3
Median Number	4

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1244984	3
BRH1244985	2
BRH1244986	0
BRH1244987	0
BRH1244988	4
BRH1244989	3
BRH1244990	0
BRH1244991	1
BRH1244992	2
BRH1267320	0
BRH1267321	9
BRH1267322	3
BRH1267323	0
BRH1244993	1
BRH1244994	1
BRH1244995	0
BRH1244996	2
BRH1244997	0
BRH1244998	4
BRH1244999	1
BRH1245000	3
BRH1245001	2
BRH1245002	3
BRH1245003	4
BRH1245004	1
BRH1245005	2
BRH1245006	0
BRH1245007	0
BRH1245008	15
BRH1245009	7
BRH1245010	9
BRH1245011	12
BRH1245012	0
BRH1245013	19
BRH1245014	0
BRH1245015	0
BRH1245016	11
BRH1245017	0
BRH1245018	0
BRH1245019	3
BRH1245020	16
BRH1245021	0

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
# of Patients w/ 0 Pos Results	18
% Subjects w/ 0 pos results	15.0

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
BRH1245022	20
BRH1245023	0
BRH1245024	3
BRH1245025	6
BRH1245026	3
BRH1245027	16
BRH1245029	0
BRH1245030	3
BRH1245031	1
BRH1245032	0
BRH1245033	4
BRH1245034	2
BRH1245035	0
BRH1245036	17
BRH1245037	0
BRH1245038	6
BRH1245039	7
BRH1245040	3
BRH1245041	0
BRH1267327	3
BRH1267329	3
BRH1267330	0
BRH1267331	1
BRH1267333	1
BRH1267334	21
BRH1267335	9
BRH1267337	2
BRH1267338	0
BRH1267339	6
BRH1267340	12
BRH1267341	0
BRH1267342	0
BRH1267343	11
BRH1267345	0
BRH1267346	0
BRH1267347	1
BRH1267349	0

No of Observations	163
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FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 90th Percentile
Average Number	4.2
Median Number	2

# of Patients w/ 0 Pos Results	51
% Subjects w/ 0 pos results	31.3

Table 5A

WO 2017/160869

PCT/US2017/022349

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
KH16-15897	1
KH16-16354	1
160905AAB0002	9
160905AAB0011	0
160905AAB0015	2
160905AAB0023	1
160905AAB0047	0
160905AAB0057	7
160905AAB0060	5
160905AAB0067	0
160905AAB0072	2
160905AAB0078	0
160905AAB0085	0
160905AAB0088	33
160905AAB0099	11
160905AAB0101	1
DLS15-15734	5
DLS15-18575	7
DLS16-31888	0
DLS16-32092	0
KH16-14191	0
KH16-14192	0
KH16-14193	2
KH16-15444	7
KH16-15445	0
KH16-15446	10
KH16-15894	0
KH16-15895	6
KH16-15896	0
KH16-16349	16
KH16-16350	8
KH16-16351	6
KH16-16352	1
KH16-16353	22
160905AAB0001	0
160905AAB0003	8
160905AAB0004	8
160905AAB0005	3
160905AAB0006	8
160905AAB0007	8
160905AAB0008	1
160905AAB0009	0

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1244900	0
BRH1244901	7
BRH1244902	1
BRH1244903	0
BRH1244904	1
BRH1244905	0
BRH1244906	5
BRH1244907	0
BRH1244908	0
BRH1244909	3
BRH1244910	2
BRH1244911	0
BRH1244912	0
BRH1244913	0
BRH1244914	6
BRH1244915	0
BRH1244916	3
BRH1244917	12
BRH1244918	1
BRH1244919	0
BRH1244920	1
BRH1244921	0
BRH1244922	12
BRH1244923	0
BRH1244924	0
BRH1244925	1
BRH1244926	12
BRH1244927	0
BRH1244928	2
BRH1244929	2
BRH1244930	0
BRH1244931	0
BRH1244932	4
BRH1244933	3
BRH1244934	5
BRH1244935	8
BRH1244936	0
BRH1244937	3
BRH1244938	2
BRH1244939	0
BRH1244940	0
BRH1244941	0

WO 2017/160869

PCT/US2017/022349

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
160905AAB0010	2
160905AAB0012	2
160905AAB0013	4
160905AAB0016	3
160905AAB0017	2
160905AAB0018	10
160905AAB0019	0
160905AAB0020	1
160905AAB0021	2
160905AAB0022	4
160905AAB0024	36
160905AAB0025	0
160905AAB0026	3
160905AAB0028	5
160905AAB0029	6
160905AAB0030	0
160905AAB0031	6
160905AAB0032	0
160905AAB0033	6
160905AAB0034	2
160905AAB0035	20
160905AAB0036	0
160905AAB0038	1
160905AAB0039	1
160905AAB0040	2
160905AAB0041	1
160905AAB0042	3
160905AAB0043	15
160905AAB0044	0
160905AAB0045	0
160905AAB0046	8
160905AAB0048	9
160905AAB0049	7
160905AAB0050	1
160905AAB0051	4
160905AAB0052	1
160905AAB0053	3
160905AAB0054	0
160905AAB0055	2
160905AAB0056	3
160905AAB0058	28
160905AAB0059	0

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1244942	5
BRH1244943	1
BRH1244944	11
BRH1244945	0
BRH1244946	4
BRH1244947	4
BRH1244948	0
BRH1244949	2
BRH1244950	0
BRH1244951	0
BRH1244952	1
BRH1244953	2
BRH1244954	0
BRH1244955	0
BRH1244956	28
BRH1244957	0
BRH1244958	1
BRH1244959	0
BRH1244960	0
BRH1244961	1
BRH1244962	0
BRH1244963	2
BRH1244964	4
BRH1244965	1
BRH1244966	1
BRH1244967	1
BRH1244968	0
BRH1244969	1
BRH1244970	2
BRH1244971	6
BRH1244972	0
BRH1244973	2
BRH1244974	1
BRH1244975	0
BRH1244976	0
BRH1244977	0
BRH1244978	0
BRH1244979	0
BRH1244980	0
BRH1244981	0
BRH1244982	0
BRH1244983	2

WO 2017/160869

PCT/US2017/022349

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
160905AAB0061	0
160905AAB0062	1
160905AAB0063	0
160905AAB0064	1
160905AAB0065	1
160905AAB0066	3
160905AAB0068	24
160905AAB0069	5
160905AAB0070	5
160905AAB0071	32
160905AAB0073	1
160905AAB0074	19
160905AAB0075	18
160905AAB0076	1
160905AAB0077	3
160905AAB0079	1
160905AAB0080	1
160905AAB0081	5
160905AAB0082	0
160905AAB0083	29
160905AAB0084	22
160905AAB0086	0
160905AAB0087	8
160905AAB0089	6
160905AAB0090	8
160905AAB0091	2
160905AAB0092	8
160905AAB0093	8
160905AAB0094	0
160905AAB0095	1
160905AAB0096	0
160905AAB0097	1
160905AAB0098	3
160905AAB0100	0
160905AAB0102	24
160905AAB0103	18

No of Observations	120
Average Number	5.5
Median Number	2

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1244984	1
BRH1244985	1
BRH1244986	0
BRH1244987	0
BRH1244988	2
BRH1244989	1
BRH1244990	0
BRH1244991	1
BRH1244992	1
BRH1267320	0
BRH1267321	7
BRH1267322	1
BRH1267323	0
BRH1244993	0
BRH1244994	0
BRH1244995	0
BRH1244996	1
BRH1244997	0
BRH1244998	3
BRH1244999	1
BRH1245000	1
BRH1245001	0
BRH1245002	1
BRH1245003	1
BRH1245004	0
BRH1245005	1
BRH1245006	0
BRH1245007	0
BRH1245008	7
BRH1245009	5
BRH1245010	3
BRH1245011	8
BRH1245012	0
BRH1245013	5
BRH1245014	0
BRH1245015	0
BRH1245016	3
BRH1245017	0
BRH1245018	0
BRH1245019	2
BRH1245020	9
BRH1245021	0

FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
# of Patients w/ 0 Pos Results	30
% Subjects w/ 0 pos results	25.0

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
BRH1245022	10
BRH1245023	0
BRH1245024	1
BRH1245025	2
BRH1245026	1
BRH1245027	10
BRH1245029	0
BRH1245030	0
BRH1245031	1
BRH1245032	0
BRH1245033	1
BRH1245034	1
BRH1245035	0
BRH1245036	7
BRH1245037	0
BRH1245038	5
BRH1245039	3
BRH1245040	0
BRH1245041	0
BRH1267327	2
BRH1267329	1
BRH1267330	0
BRH1267331	1
BRH1267333	0
BRH1267334	9
BRH1267335	5
BRH1267337	1
BRH1267338	0
BRH1267339	1
BRH1267340	9
BRH1267341	0
BRH1267342	0
BRH1267343	9
BRH1267345	0
BRH1267346	0
BRH1267347	0
BRH1267349	0
No of Observations	163

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

NON-FIBROMYALGIA POPULATION	
Sample ID	# of Positive Results Based on 95th Percentile
Average Number	2.0
Median Number	1

# of Patients w/ 0 Pos Results	76
% Subjects w/ 0 pos results	46.6

Table 5B

Variable	Fibromyalgia_90th_percentile Fibromyalgia_90th_percentile	
Sample size	120	
Lowest value	0.0000	
Highest value	37.0000	
Arithmetic mean	8.2500	
95% CI for the mean	6.4820 to 10.0180	
Median	4.0000	
95% CI for the median	3.0000 to 7.0000	
Variance	95.6681	
Standard deviation	9.7810	
Relative standard deviation	1.1856 (118.56%)	
Standard error of the mean	0.8929	
Coefficient of Skewness	1.5400 (P<0.0001)	
Coefficient of Kurtosis	1.5020 (P=0.0144)	
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 1.0000
25	1.0000	1.0000 to 2.0000
75	11.5000	9.0000 to 14.5316
90	27.0000	15.0000 to 32.5127
95	32.5000	27.4483 to 35.6776
97.5	34.5000	

Table 6A

Variable	Fibromyalgia_95th_percentile Fibromyalgia 95th percentile	
Sample size	120	
Lowest value	0.0000	
Highest value	36.0000	
Arithmetic mean	5.5083	
95% CI for the mean	4.0943 to 6.9223	
Median	2.0000	
95% CI for the median	1.0000 to 3.2140	
Variance	61.1932	
Standard deviation	7.8226	
Relative standard deviation	1.4201 (142.01%)	
Standard error of the mean	0.7141	
Coefficient of Skewness	2.1087 (P<0.0001)	
Coefficient of Kurtosis	4.1388 (P<0.0001)	
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	0.5000	0.0000 to 1.0000
75	7.5000	5.9915 to 8.0000
90	18.0000	9.0000 to 24.0000
95	24.0000	18.4483 to 32.6776
97.5	30.5000	

Table 6B

Summary statistics

Variable	Non_Fibromyalgia_90th_percentile_1 Non-Fibromyalgia 90th percentile_1	
Back-transformed after logarithmic transformation.		
Sample size	163	
Lowest value	0.1000	
Highest value	35.0000	
Geometric mean	1.2211	
95% CI for the mean	0.9127 to 1.6337	
Median	2.0000	
95% CI for the median	1.0000 to 3.0000	
Coefficient of Skewness	-0.2225 (P=0.2362)	
Coefficient of Kurtosis	-1.3403 (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 1.0000
75	6.0000	4.0000 to 7.0000
90	12.0000	9.3687 to 17.0000
95	17.6748	15.0000 to 22.1821
97.5	21.0000	17.2527 to 33.6228

Table 7A

Summary statistics

Variable	Nor_Fibromyalgia_95th_percentile Nor-Fibromyalgia 95th percentile	
Sample size	163	
Lowest value	0.0000	
Highest value	28.0000	
Arithmetic mean	1.9939	
95% CI for the mean	1.4489 to 2.5388	
Median	1.0000	
95% CI for the median	0.0000 to 1.0000	
Variance	12.4135	
Standard deviation	3.5233	
Relative standard deviation	1.7671 (176.71%)	
Standard error of the mean	0.2760	
Coefficient of Skewness	3.4842 (P<0.0001)	
Coefficient of Kurtosis	18.5361 (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	2.0000	1.6997 to 3.3243
90	7.0000	5.0000 to 9.0000
95	9.0000	7.0000 to 12.0000
97.5	11.4250	9.0000 to 24.5845

Table 7B

Variable	Fibromyalgia_90th_percentile_1	Fibromyalgia 90th percentile_1
Back-transformed after logarithmic transformation.		
Sample size		120
Lowest value		0.1000
Highest value		37.0000
Geometric mean		3.0394
95% CI for the mean		2.2038 to 4.1919
Median		4.0000
95% CI for the median		3.0000 to 7.0000
Coefficient of Skewness		-0.7199 (P=0.0021)
Coefficient of Kurtosis		-0.4099 (P=0.3098)
D'Agostino-Pearson test for Normal distribution		reject Normality (P=0.0053)
Percentiles		95% Confidence interval
2.5	0.10000	
5	0.10000	0.10000 to 0.10000
10	0.10000	0.10000 to 1.0000
25	1.0000	1.0000 to 2.0000
75	11.4891	9.0000 to 14.5231
90	27.0000	15.0000 to 32.5089
95	32.4962	27.4438 to 35.6745
97.5	34.4964	

Table 8A

Variable	Fibromyalgia_95th_percentile_1	Fibromyalgia 95th percentile_1
Back-transformed after logarithmic transformation.		
Sample size		120
Lowest value		0.1000
Highest value		36.0000
Geometric mean		1.6485
95% CI for the mean		1.1746 to 2.3137
Median		2.0000
95% CI for the median		1.0000 to 3.1905
Coefficient of Skewness		-0.3573 (P=0.1044)
Coefficient of Kurtosis		-1.0939 (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	0.3162	0.10000 to 1.0000
75	7.4833	5.9907 to 8.0000
90	18.0000	9.0000 to 24.0000
95	24.0000	18.4416 to 32.6742
97.5	30.4631	

Table 8B

Summary statistics		
Variable	Non_Fibromyalgia_90th_percentile_1 Non-Fibromyalgia 90th percentile_1	
Back-transformed after logarithmic transformation.		
Sample size	163	
Lowest value	0.1000	
Highest value	35.0000	
Geometric mean	1.2211	
95% CI for the mean	0.9127 to 1.6337	
Median	2.0000	
95% CI for the median	1.0000 to 3.0000	
Coefficient of Skewness	-0.2225 (P=0.2362)	
Coefficient of Kurtosis	-1.3403 (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 1.0000
75	6.0000	4.0000 to 7.0000
90	12.0000	9.3687 to 17.0000
95	17.6748	15.0000 to 22.1821
97.5	21.0000	17.2527 to 33.6228

Table 9A

Variable	Non_Fibromyalgia_95th_percentile_1	Non-Fibromyalgia 95th percentile_1
Back-transformed after logarithmic transformation.		
Sample size		163
Lowest value		0.1000
Highest value		28.0000
Geometric mean		0.5496
95% CI for the mean		0.4209 to 0.7177
Median		1.0000
95% CI for the median		0.10000 to 1.0000
Coefficient of Skewness		0.3058 (P=0.1067)
Coefficient of Kurtosis		-1.3991 (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	2.0000	1.6241 to 3.2934
90	7.0000	5.0000 to 9.0000
95	9.0000	7.0000 to 12.0000
97.5	11.4144	9.0000 to 23.3672

Table 9B

Independent samples t-test		
Sample 1		
Variable	Fibromyalgia_90th_percentile_1 Fibromyalgia 90th percentile_1	
Sample 2		
Variable	Non_Fibromyalgia_90th_percentile_1 Non-Fibromyalgia 90th percentile_1	
Back-transformed after logarithmic transformation.		
	Sample 1	Sample 2
Sample size	120	163
Geometric mean	3.0394	1.2211
95% CI for the mean	2.2038 to 4.1919	0.9127 to 1.6337
Variance of Logs	0.5966	0.6681
F-test for equal variances	P = 0.515	
T-test (assuming equal variances)		
Difference on Log-transformed scale		
Difference	-0.3960	
Standard Error	0.09606	
95% CI of difference	-0.5851 to -0.2069	
Test statistic t	-4.123	
Degrees of Freedom (DF)	281	
Two-tailed probability	P < 0.0001	
Back-transformed results		
Ratio of geometric means	0.4018	
95% CI of ratio	0.2499 to 0.6210	

Table 10A

Independent samples t-test		
Sample 1		
Variable	Fibromyalgia_95th_percentile_1 Fibromyalgia_95th_percentile_1	
Sample 2		
Variable	Non_Fibromyalgia_95th_percentile_1 Non-Fibromyalgia_95th_percentile_1	
Back-transformed after logarithmic transformation.		
	Sample 1	Sample 2
Sample size	120	163
Geometric mean	1.6485	0.5496
95% CI for the mean	1.1746 to 2.3137	0.4209 to 0.7177
Variance of Logs	0.6633	0.5616
F test for equal variances	P = 0.324	
T-test (assuming equal variances)		
Difference on Log-transformed scale		
Difference	-0.4771	
Standard Error	0.09353	
95% CI of difference	-0.6612 to -0.2929	
Test statistic t	-5.100	
Degrees of Freedom (DF)	281	
Two-tailed probability	P < 0.0001	
Back-transformed results		
Ratio of geometric means	0.3334	
95% CI of ratio	0.2182 to 0.5094	

Table 10B

Mann-Whitney test (independent samples)

Sample 1		
Variable	Fibromyalgia_90th_percentile Fibromyalgia 90th percentile	
Sample 2		
Variable	Non_Fibromyalgia_90th_percentile Non Fibromyalgia 90th percentile	
	Sample 1	Sample 2
Sample size	120	163
Lowest value	0.0000	0.0000
Highest value	37.0000	35.0000
Median	4.0000	2.0000
95% CI for the median	3.0000 to 7.0000	1.0000 to 3.0000
Interquartile range	1.0000 to 11.5000	0.0000 to 6.0000

Mann-Whitney test (independent samples)

Average rank of first group	164.5530
Average rank of second group	125.3938
Mann-Whitney U	7074.00
Test statistic Z (corrected for ties)	4.015
Two-tailed probability	P = 0.0001

Table 11A**Mann-Whitney test (Independent samples)**

Sample 1		
Variable	Fibromyalgia_95th_percentile Fibromyalgia 95th percentile	
Sample 2		
Variable	Non_Fibromyalgia_95th_percentile Non-Fibromyalgia 95th percentile	
	Sample 1	Sample 2
Sample size	120	163
Lowest value	0.0000	0.0000
Highest value	36.0000	28.0000
Median	2.0000	1.0000
95% CI for the median	1.0000 to 3.2140	0.0000 to 1.0000
Interquartile range	0.5000 to 7.5000	0.0000 to 2.0000

Mann-Whitney test (independent samples)

Average rank of first group	168.8125
Average rank of second group	122.2607
Mann-Whitney U	6562.50
Test statistic Z (corrected for ties)	4.876
Two-tailed probability	P < 0.0001

Table 11B

ROC curve

Variable	Fibromyalgia_Test_90th Fibromyalgia_Test_90th
Classification variable	Diagnosis__1_Fibromyalgia_0_Non_Fibromyalgia_ Diagnosis(1_Fibromyalgia 0_Non-Fibromyalgia)
Sample size	283
Positive group ^a	120 (42.40%)
Negative group ^b	163 (57.60%)
^a Diagnosis__1_Fibromyalgia_0_Non_Fibromyalgia_ = 1 ^b Diagnosis__1_Fibromyalgia_0_Non_Fibromyalgia_ = 0	
Disease prevalence (%)	unknown

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.638
Standard Error ^a	0.0330
95% Confidence interval ^b	0.579 to 0.694
z statistic	4.188
Significance level P (Area=0.5)	<0.0001

^a DeLong et al., 1988^b Binomial exact**Youden index**

Youden index J	0.2248
95% Confidence interval ^a	0.1067 to 0.3070
Associated criterion	>3
95% Confidence interval ^a	>0 to >7
Sensitivity	55.00
Specificity	67.48

^a ROC bootstrap confidence interval (1000 iterations; random number seed 978)**Table 12A**

ROC curve

Variable	Fibromyalgia_Test_95th Fibromyalgia_Test_95th
Classification variable	Diagnosis__1_Fibromyalgia_0_Non_Fibromyalgia_ Diagnosis(1_Fibromyalgia_0_Non-Fibromyalgia)
Sample size	283
Positive group ^a	120 (42.40%)
Negative group ^b	163 (57.60%)
^a Diagnosis__1_Fibromyalgia_0_Non_Fibromyalgia_ = 1 ^b Diagnosis__1_Fibromyalgia_0_Non_Fibromyalgia_ = 0	
Disease prevalence (%)	unknown

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.664
Standard Error ^a	0.0320
95% Confidence interval ^b	0.606 to 0.719
z statistic	5.139
Significance level P (Area=0.5)	<0.0001

^a DeLong et al., 1988^b Binomial exact**Youden index**

Youden index J	0.2560
95% Confidence interval ^a	0.1424 to 0.3355
Associated criterion	>1
95% Confidence interval ^a	>0 to >3
Sensitivity	57.50
Specificity	68.10

^a BC_a bootstrap confidence interval (1000 iterations; random number seed: 978).**Table 12B**

Performance Metrics in Predicting Fibromyalgia 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	0.88	0.26	0.65	0.57	0.64
	2	0.75	0.42	0.67	0.52	0.62
	3	0.64	0.51	0.68	0.48	0.59
	4	0.58	0.61	0.70	0.48	0.59
	5	0.53	0.67	0.71	0.47	0.58
	6	0.50	0.70	0.73	0.47	0.58
	7	0.47	0.74	0.74	0.47	0.57
	8	0.42	0.78	0.75	0.46	0.56
	9	0.38	0.80	0.75	0.45	0.55
	10	0.34	0.82	0.75	0.44	0.53
	11	0.31	0.83	0.74	0.43	0.51
	12	0.28	0.84	0.73	0.43	0.50
	13	0.25	0.86	0.73	0.42	0.48
	14	0.22	0.87	0.72	0.41	0.47
	15	0.19	0.88	0.71	0.41	0.46
	16	0.17	0.90	0.73	0.41	0.45
	17	0.16	0.91	0.75	0.41	0.45
	18	0.15	0.93	0.77	0.41	0.45
	19	0.14	0.95	0.80	0.41	0.45
	20	0.14	0.95	0.82	0.41	0.45
	21	0.13	0.97	0.86	0.41	0.46
	22	0.13	0.98	0.90	0.42	0.46
	23	0.13	0.98	0.91	0.42	0.46
	24	0.13	1.00	1.00	0.42	0.46
	25	0.12	1.00	1.00	0.42	0.46
	26	0.11	1.00	1.00	0.42	0.46
	27	0.11	1.00	1.00	0.41	0.45
	28	0.10	1.00	1.00	0.41	0.45
	29	0.09	1.00	1.00	0.41	0.44
	30	0.08	1.00	1.00	0.41	0.44
	31	0.07	1.00	1.00	0.41	0.43
	32	0.06	1.00	1.00	0.40	0.43

<i>Sex</i>	<i>No. of Positive Foods as Cutoff</i>	<i>Sensitivity</i>	<i>Specificity</i>	<i>Positive Predictive Value</i>	<i>Negative Predictive Value</i>	<i>Overall Percent Agreement</i>
	33	0.05	1.00	1.00	0.40	0.42
	34	0.04	1.00	1.00	0.40	0.41
	35	0.03	1.00	1.00	0.40	0.41
	36	0.02	1.00	1.00	0.39	0.40
	37	0.00	1.00	1.00	0.39	0.39
	38	0.00	1.00	1.00	0.39	0.39
	39	0.00	1.00	1.00	0.39	0.39
	40	0.00	1.00	1.00	0.39	0.39
	41	0.00	1.00	.	0.39	0.39
	42	0.00	1.00	.	0.39	0.39
	43	0.00	1.00	.	0.39	0.39

Table 13A

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

<i>Sex</i>	<i>No. of Positive Foods as Cutoff</i>	<i>Sensitivity</i>	<i>Specificity</i>	<i>Positive Predictive Value</i>	<i>Negative Predictive Value</i>	<i>Overall Percent Agreement</i>
MALE	1	0.86	0.25	0.16	0.92	0.34
	2	0.73	0.41	0.17	0.90	0.46
	3	0.67	0.54	0.19	0.91	0.56
	4	0.50	0.62	0.18	0.88	0.60
	5	0.36	0.68	0.17	0.87	0.64
	6	0.33	0.73	0.17	0.87	0.67
	7	0.31	0.76	0.18	0.87	0.70
	8	0.30	0.81	0.20	0.88	0.73
	9	0.30	0.83	0.22	0.88	0.76
	10	0.29	0.86	0.25	0.88	0.77
	11	0.27	0.88	0.25	0.88	0.79
	12	0.25	0.89	0.27	0.88	0.80
	13	0.20	0.90	0.27	0.87	0.81
	14	0.18	0.92	0.25	0.87	0.81
	15	0.14	0.92	0.25	0.87	0.81
	16	0.11	0.92	0.20	0.87	0.81
	17	0.10	0.93	0.20	0.86	0.82
	18	0.10	0.94	0.20	0.86	0.82
	19	0.09	0.95	0.20	0.86	0.82
	20	0.09	0.95	0.25	0.86	0.83
	21	0.08	0.95	0.25	0.86	0.83
	22	0.08	0.95	0.25	0.86	0.83
	23	0.08	0.97	0.25	0.86	0.84
	24	0.08	0.97	0.25	0.86	0.84
	25	0.08	0.97	0.33	0.86	0.84
	26	0.08	0.98	0.33	0.86	0.85
	27	0.08	0.98	0.33	0.86	0.85
	28	0.08	0.98	0.33	0.86	0.85
	29	0.08	0.98	0.42	0.86	0.85
	30	0.08	0.98	0.50	0.86	0.85
	31	0.08	0.98	0.50	0.86	0.85

<i>Sex</i>	<i>No. of Positive Foods as Cutoff</i>	<i>Sensitivity</i>	<i>Specificity</i>	<i>Positive Predictive Value</i>	<i>Negative Predictive Value</i>	<i>Overall Percent Agreement</i>
	32	0.08	0.98	0.50	0.86	0.86
	33	0.08	0.98	0.50	0.86	0.86
	34	0.08	0.98	0.50	0.86	0.86
	35	0.08	0.98	0.50	0.86	0.86
	36	0.00	1.00	0.50	0.86	0.86
	37	0.00	1.00	0.00	0.86	0.86
	38	0.00	1.00	0.00	0.86	0.86
	39	0.00	1.00	0.00	0.86	0.86
	40	0.00	1.00	0.00	0.86	0.86
	41	0.00	1.00	0.00	0.86	0.86
	42	0.00	1.00	1.00	0.86	0.86
	43	0.00	1.00	.	0.86	0.86

Table 13B

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

<i>Sex</i>	<i>No. of Positive Foods as Cutoff</i>	<i>Sensitivity</i>	<i>Specificity</i>	<i>Positive Predictive Value</i>	<i>Negative Predictive Value</i>	<i>Overall Percent Agreement</i>
FEMALE	1	0.80	0.41	0.68	0.56	0.65
	2	0.63	0.58	0.70	0.50	0.61
	3	0.53	0.68	0.73	0.48	0.59
	4	0.46	0.75	0.74	0.47	0.57
	5	0.41	0.78	0.74	0.46	0.56
	6	0.36	0.81	0.75	0.45	0.54
	7	0.32	0.83	0.75	0.44	0.52
	8	0.27	0.85	0.74	0.43	0.50
	9	0.22	0.86	0.72	0.41	0.47
	10	0.18	0.89	0.72	0.41	0.46
	11	0.16	0.91	0.75	0.41	0.46
	12	0.14	0.95	0.80	0.41	0.46
	13	0.14	0.96	0.85	0.41	0.46
	14	0.13	0.98	0.90	0.42	0.46
	15	0.13	1.00	1.00	0.42	0.46
	16	0.13	1.00	1.00	0.42	0.46
	17	0.12	1.00	1.00	0.42	0.46
	18	0.12	1.00	1.00	0.42	0.46
	19	0.11	1.00	1.00	0.42	0.45
	20	0.10	1.00	1.00	0.41	0.45
	21	0.09	1.00	1.00	0.41	0.45
	22	0.09	1.00	1.00	0.41	0.44
	23	0.08	1.00	1.00	0.41	0.44
	24	0.07	1.00	1.00	0.41	0.43
	25	0.06	1.00	1.00	0.40	0.43
	26	0.05	1.00	1.00	0.40	0.42
	27	0.04	1.00	1.00	0.40	0.42
	28	0.03	1.00	1.00	0.40	0.41
	29	0.03	1.00	1.00	0.40	0.41
	30	0.03	1.00	1.00	0.39	0.41
	31	0.02	1.00	1.00	0.39	0.40

<i>Sex</i>	<i>No. of Positive Foods as Cutoff</i>	<i>Sensitivity</i>	<i>Specificity</i>	<i>Positive Predictive Value</i>	<i>Negative Predictive Value</i>	<i>Overall Percent Agreement</i>
	32	0.02	1.00	1.00	0.39	0.40
	33	0.01	1.00	1.00	0.39	0.40
	34	0.01	1.00	1.00	0.39	0.40
	35	0.01	1.00	1.00	0.39	0.39
	36	0.00	1.00	1.00	0.39	0.39
	37	0.00	1.00	1.00	0.39	0.39
	38	0.00	1.00	.	0.39	0.39
	39	0.00	1.00	.	0.39	0.39
	40	0.00	1.00	.	0.39	0.39
	41	0.00	1.00	.	0.39	0.39
	42	0.00	1.00	.	0.39	0.39
	43	0.00	1.00	.	0.39	0.39

Table 14A

Performance Metrics in Predicting Fibromyalgia 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	0.71	0.43	0.17	0.90	0.47
	2	0.55	0.62	0.19	0.89	0.61
	3	0.36	0.73	0.18	0.88	0.67
	4	0.31	0.79	0.20	0.87	0.72
	5	0.30	0.83	0.23	0.88	0.75
	6	0.25	0.86	0.23	0.88	0.77
	7	0.22	0.88	0.25	0.88	0.79
	8	0.21	0.91	0.29	0.88	0.81
	9	0.18	0.92	0.29	0.87	0.82
	10	0.14	0.93	0.25	0.87	0.82
	11	0.10	0.94	0.25	0.87	0.82
	12	0.10	0.95	0.25	0.86	0.82
	13	0.09	0.95	0.25	0.86	0.83
	14	0.08	0.97	0.25	0.86	0.84
	15	0.08	0.97	0.33	0.86	0.84
	16	0.08	0.98	0.33	0.86	0.85
	17	0.08	0.98	0.33	0.86	0.85
	18	0.08	0.98	0.50	0.86	0.85
	19	0.08	0.98	0.50	0.86	0.86
	20	0.08	0.98	0.50	0.86	0.86
	21	0.08	0.98	0.50	0.86	0.86
	22	0.08	0.98	0.50	0.86	0.86
	23	0.08	0.98	0.50	0.86	0.86
	24	0.08	0.98	0.50	0.86	0.86
	25	0.08	0.98	0.50	0.86	0.86
	26	0.08	0.99	0.50	0.86	0.86
	27	0.08	1.00	0.50	0.86	0.86
	28	0.08	1.00	1.00	0.86	0.86
	29	0.08	1.00	1.00	0.86	0.86
	30	0.08	1.00	1.00	0.86	0.86

<i>Sex</i>	<i>No. of Positive Foods as Cutoff</i>	<i>Sensitivity</i>	<i>Specificity</i>	<i>Positive Predictive Value</i>	<i>Negative Predictive Value</i>	<i>Overall Percent Agreement</i>
	31	0.08	1.00	1.00	0.86	0.86
	32	0.08	1.00	1.00	0.86	0.87
	33	0.00	1.00	1.00	0.86	0.86
	34	0.00	1.00	1.00	0.86	0.86
	35	0.00	1.00	1.00	0.86	0.86
	36	0.00	1.00	0.75	0.86	0.86
	37	0.00	1.00	.	0.86	0.86
	38	0.00	1.00	.	0.86	0.86
	39	0.00	1.00	.	0.86	0.86
	40	0.00	1.00	.	0.86	0.86
	41	0.00	1.00	.	0.86	0.86
	42	0.00	1.00	.	0.86	0.86
	43	0.00	1.00	.	0.86	0.86

Table 14B

CLAIMS

What is claimed is:

1. A test kit with for testing food intolerance in patients diagnosed with or suspected to have Fibromyalgia, 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 Fibromyalgia with assay values of a second patient test cohort that is not diagnosed with or suspected of having Fibromyalgia.
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 1-43 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 1-43 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 1-43 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 1-43 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 Fibromyalgia, comprising:

contacting a food preparation with a bodily fluid of a patient that is diagnosed with or suspected to have Fibromyalgia, 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 1-43 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 1-43 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 90th 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 90th percentile value.
46. A method of generating a test for food intolerance in patients diagnosed with or suspected to have Fibromyalgia, 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 Fibromyalgia and bodily fluids of a control group not diagnosed with or not suspected to have Fibromyalgia;
 - 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 1-43 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 1-43 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 1-43 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 1-43 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 1-43 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 1-43 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 90th percentile rank.
63. The method of any of claims 46-61 wherein the predetermined percentile rank is an at least 90th 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 Fibromyalgia 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 Fibromyalgia 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 Fibromyalgia 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 Fibromyalgia 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 Fibromyalgia, 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 1-43 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 1-43 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 1-43 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 1-43 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.

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

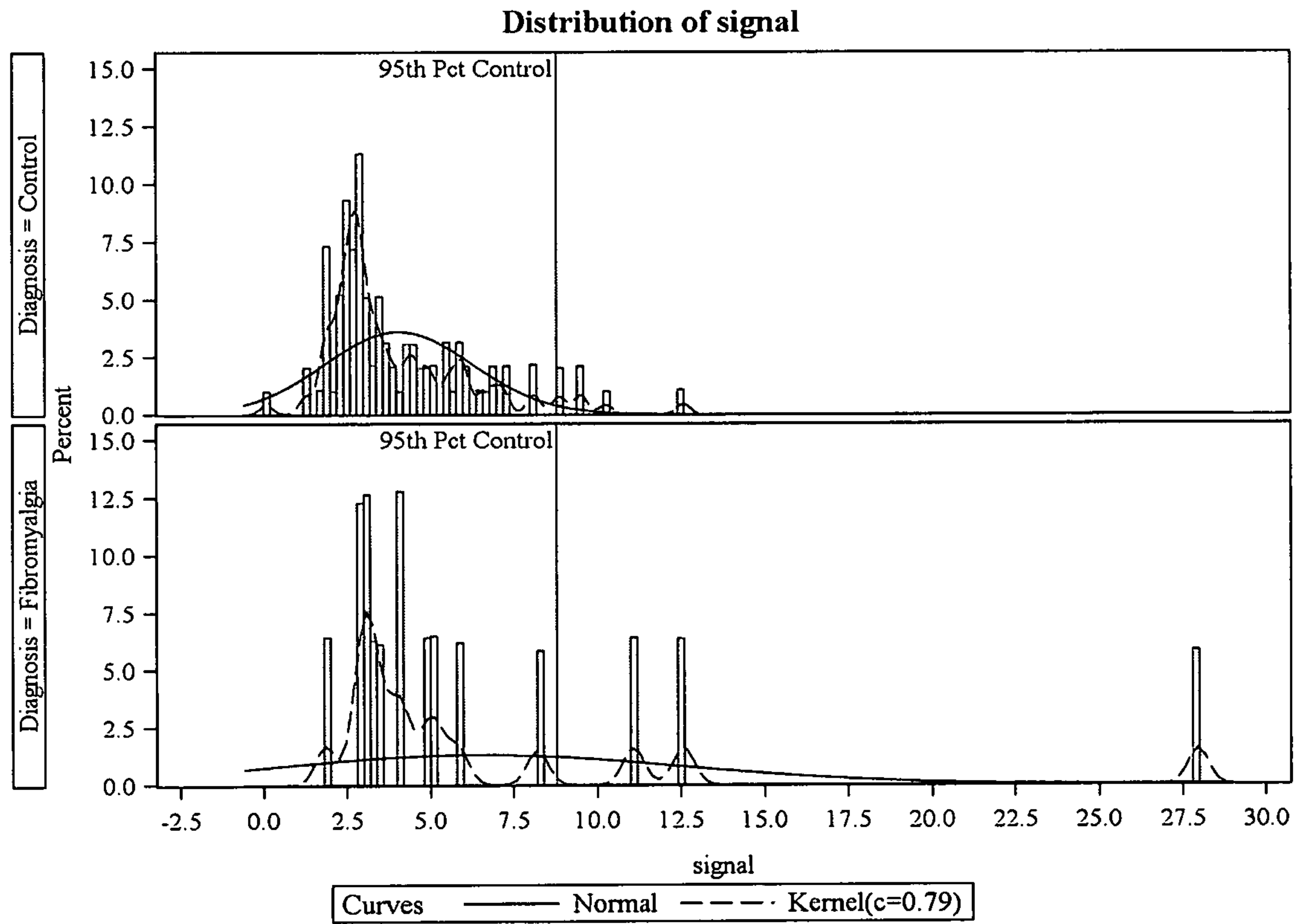


Figure 1A

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control Cutpoint
across 1000 Bootstrapped Samples***

Sex=MALE Food=Almond

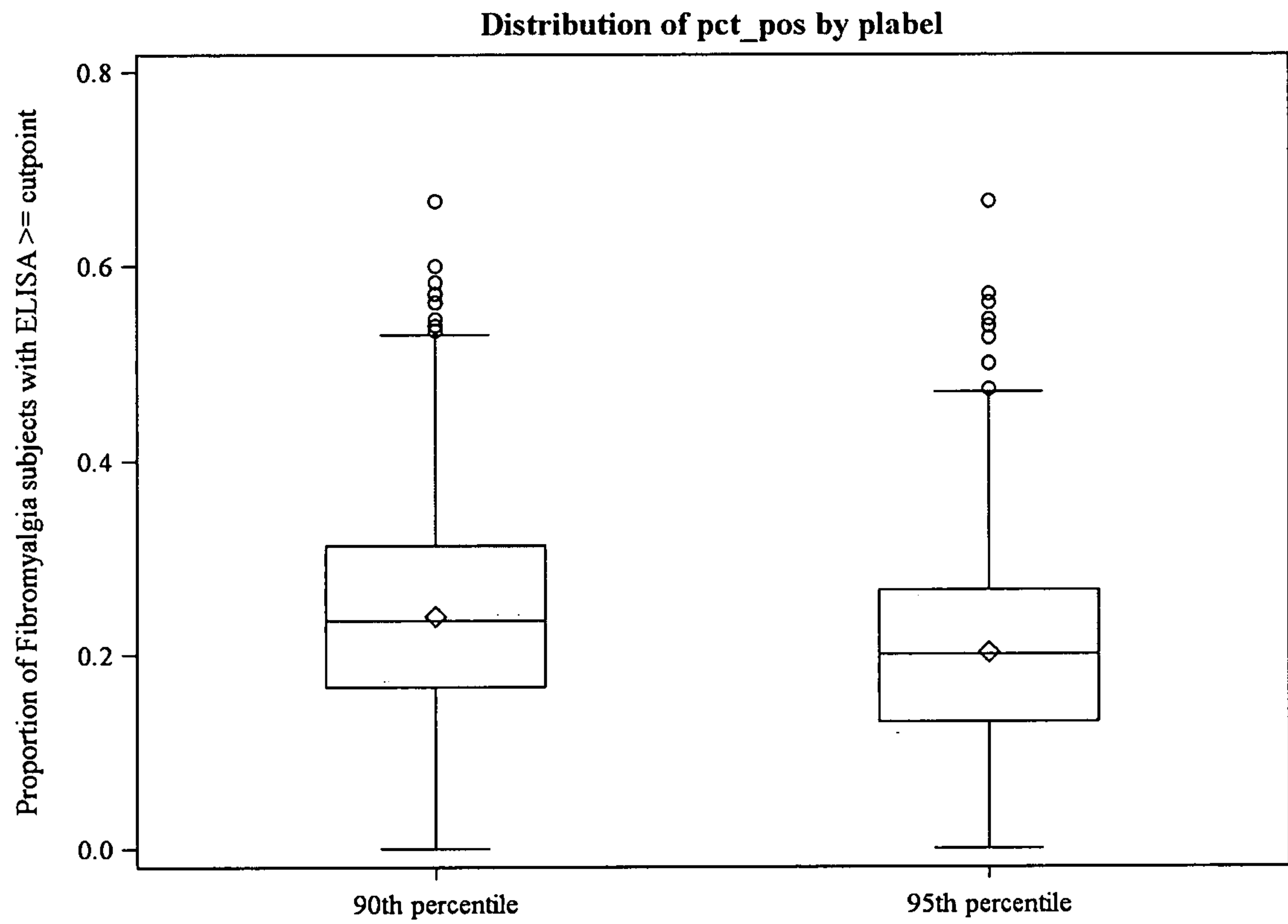


Figure 1B

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

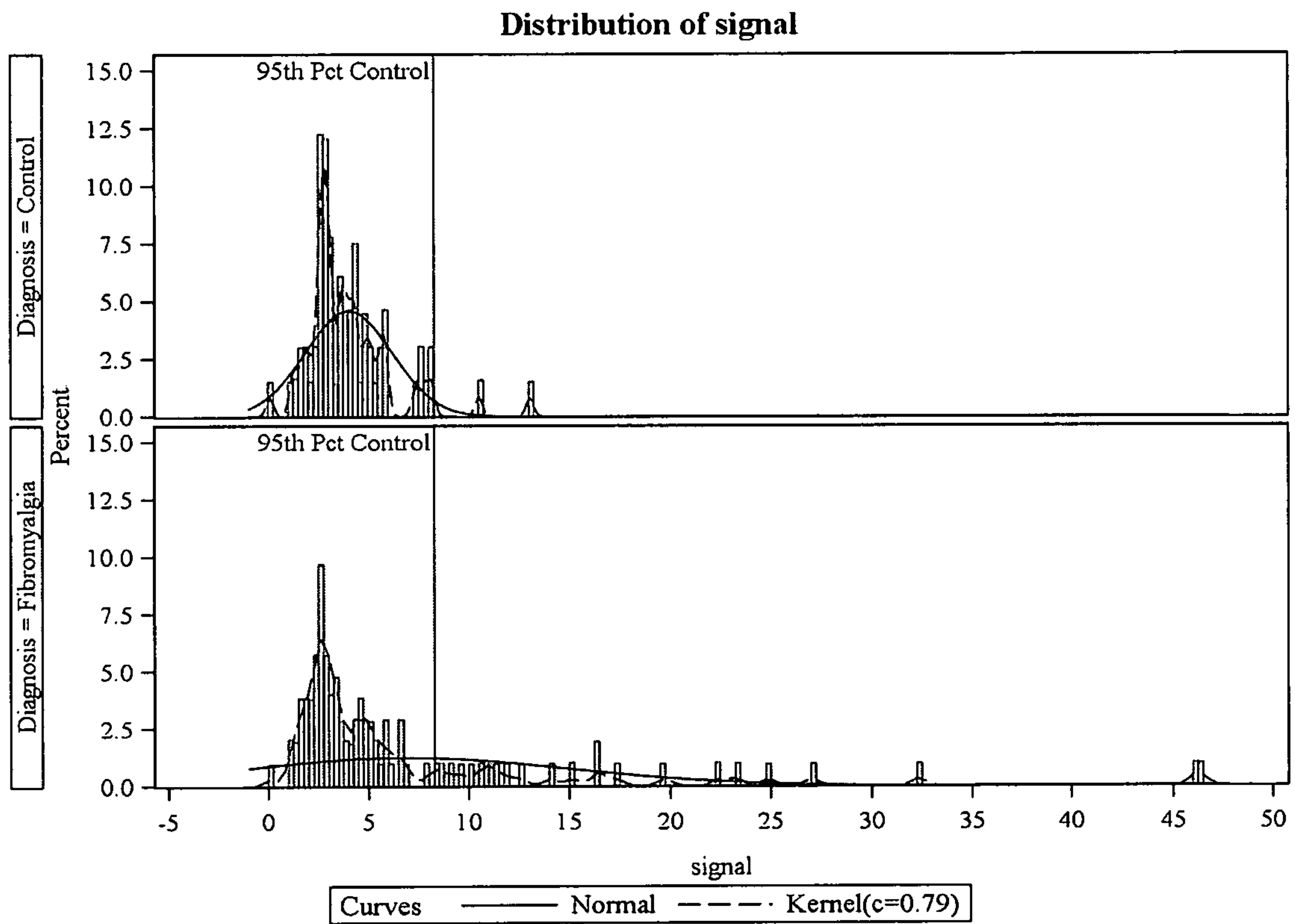


Figure 1C

*Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples*

Sex=FEMALE Food=Almond

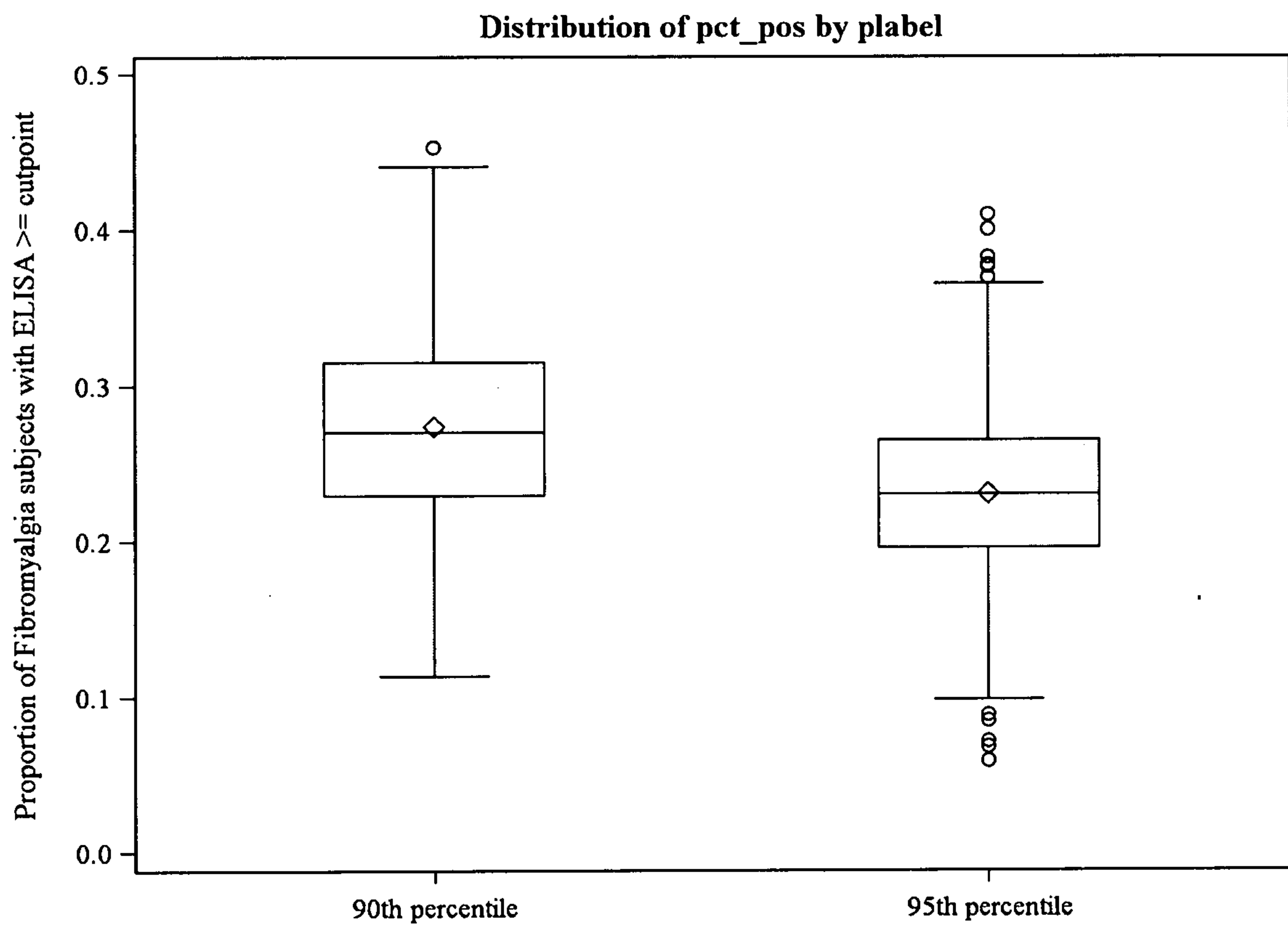
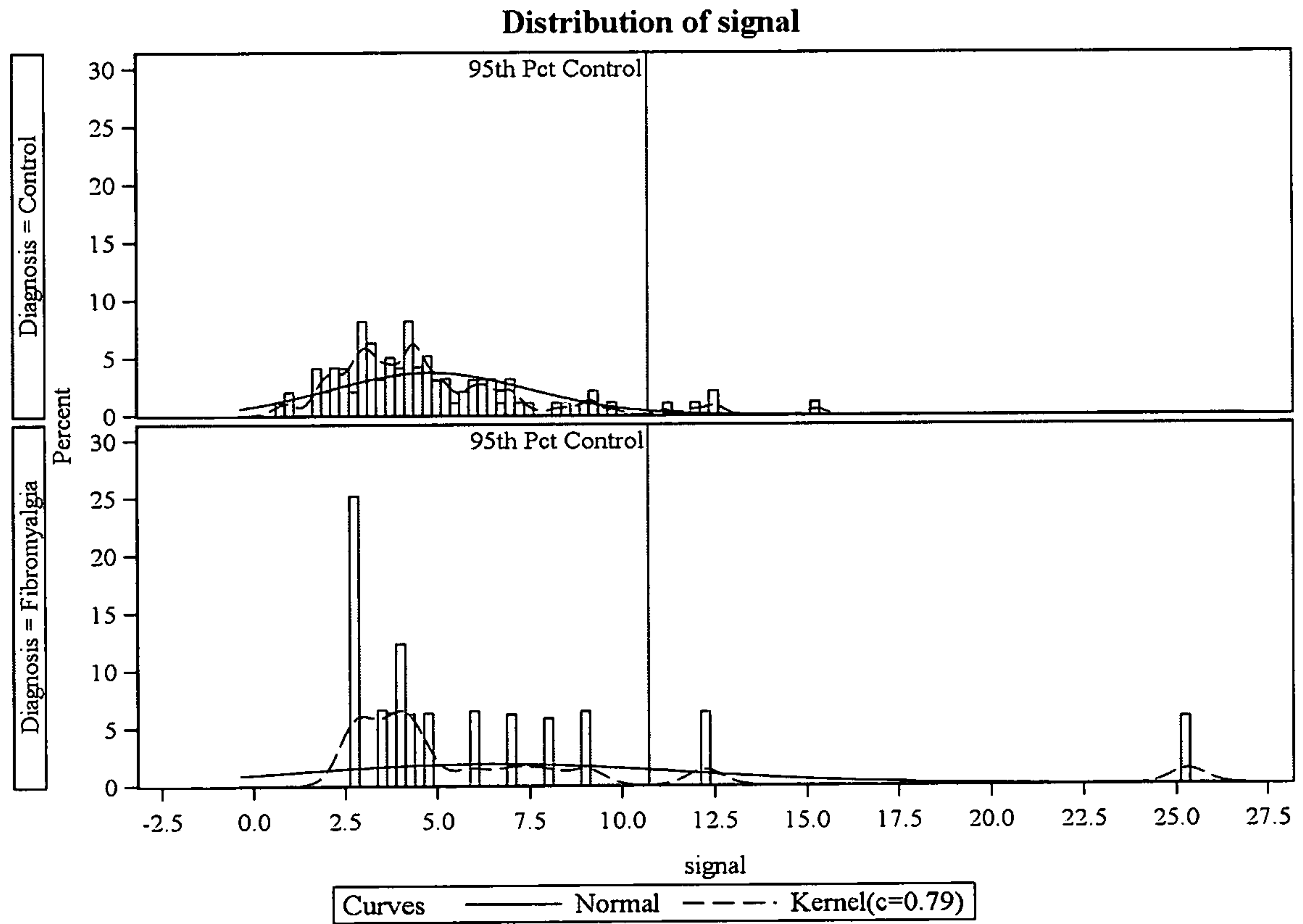


Figure 1D

*Distribution of ELISA Signal Scores by Diagnosis**Sex=MALE Food=Rye***Figure 2A**

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples***

Sex=MALE Food=Rye

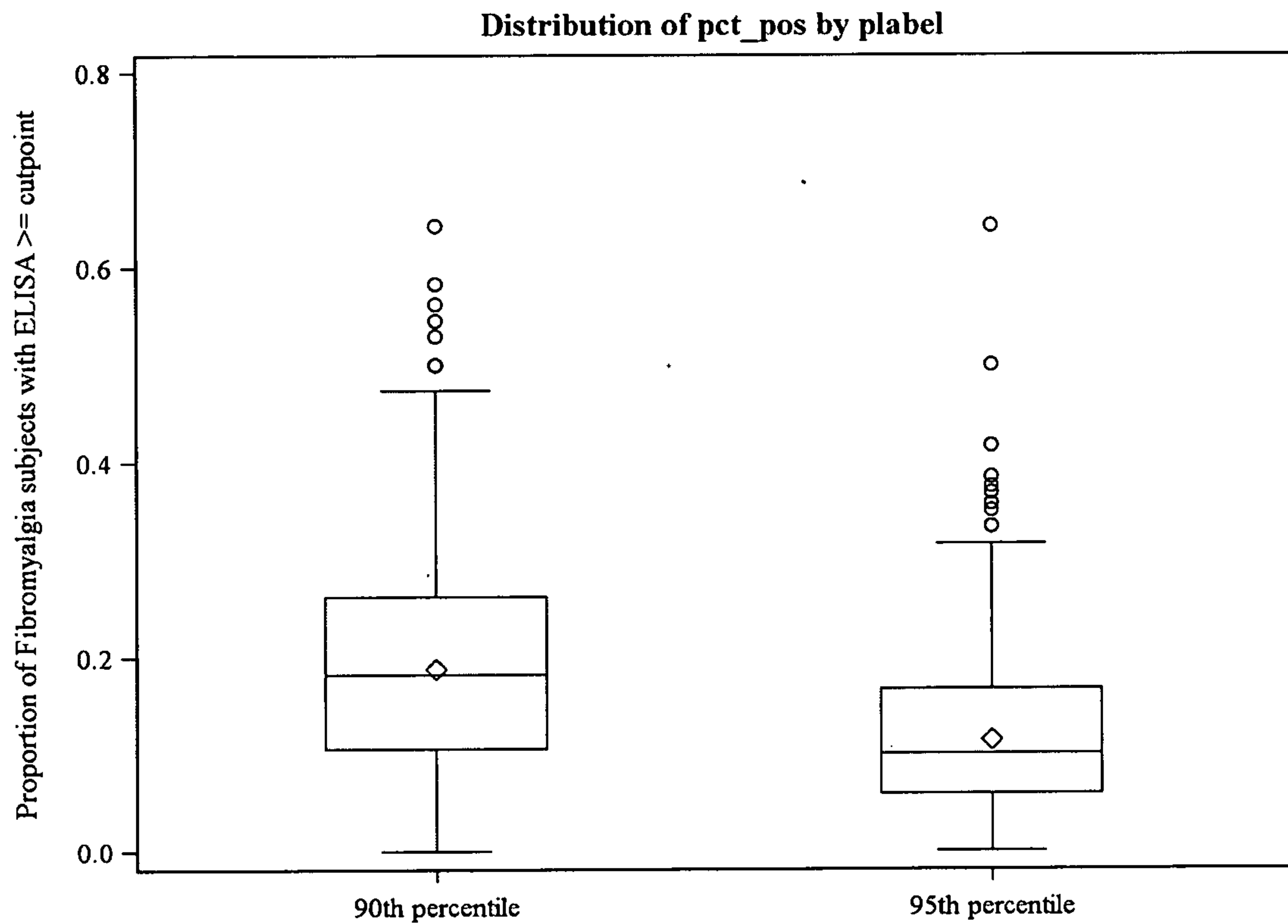
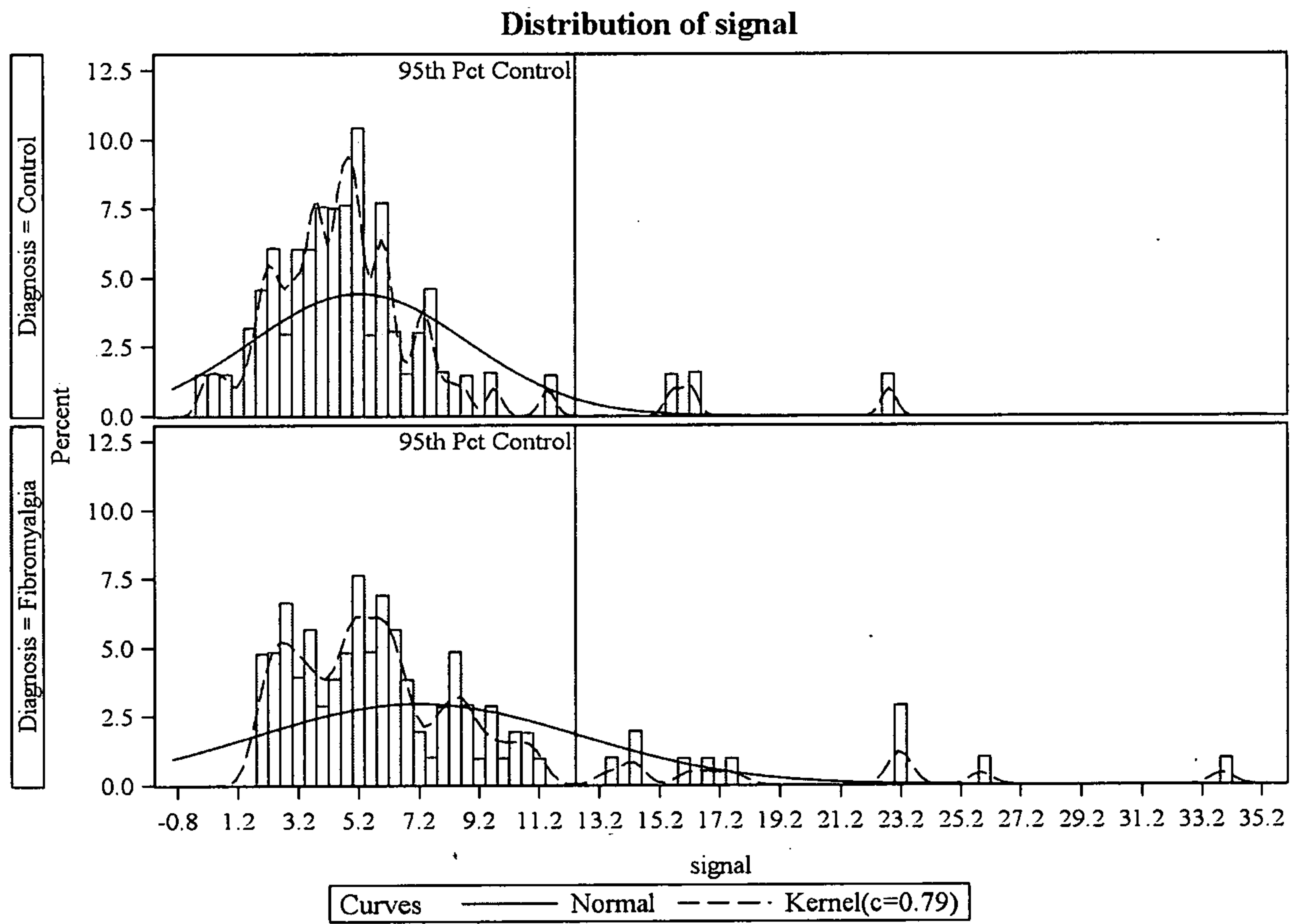


Figure 2B

*Distribution of ELISA Signal Scores by Diagnosis**Sex=FEMALE Food=Rye***Figure 2C**

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples***

Sex=FEMALE Food=Rye

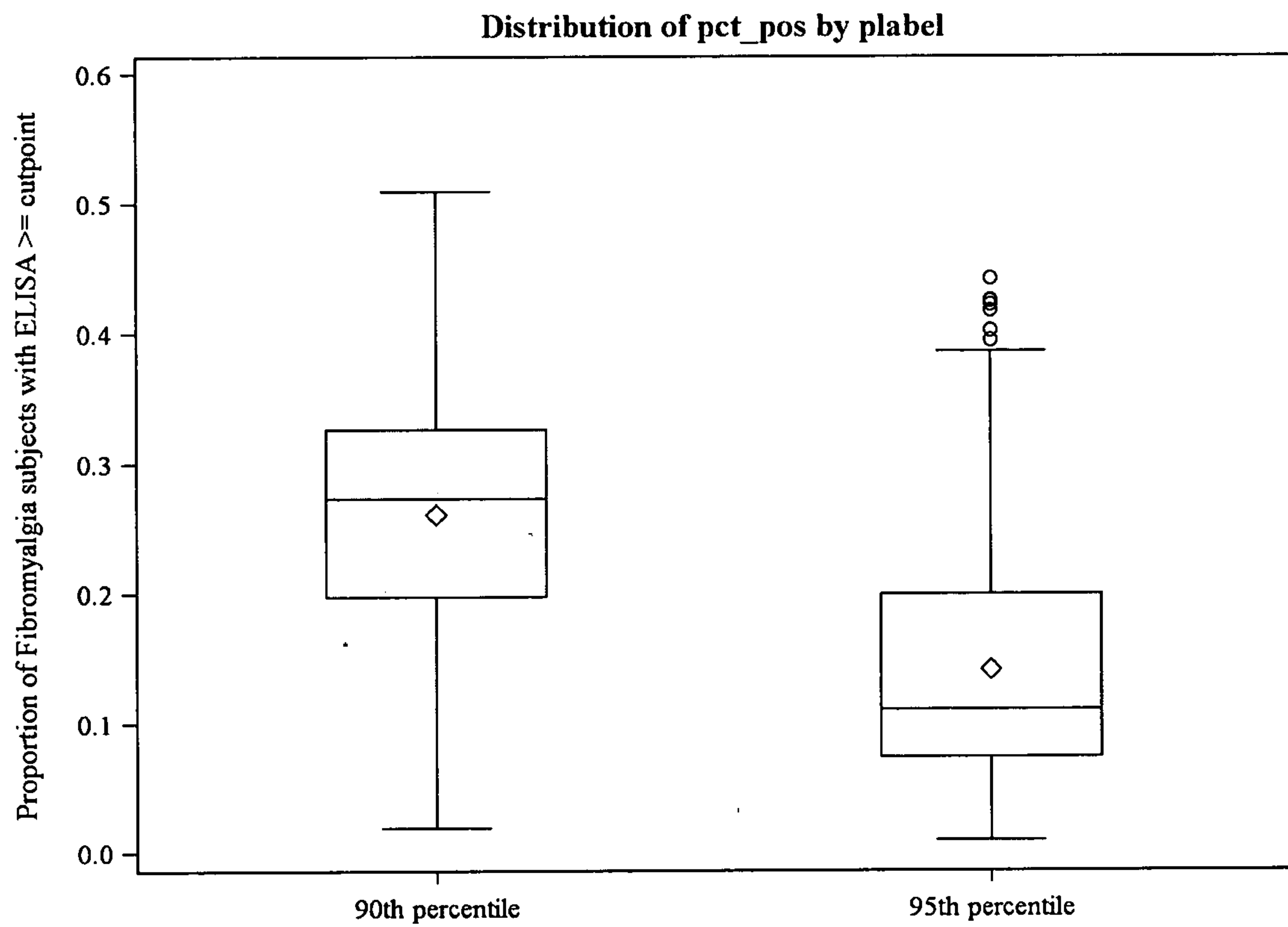


Figure 2D

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

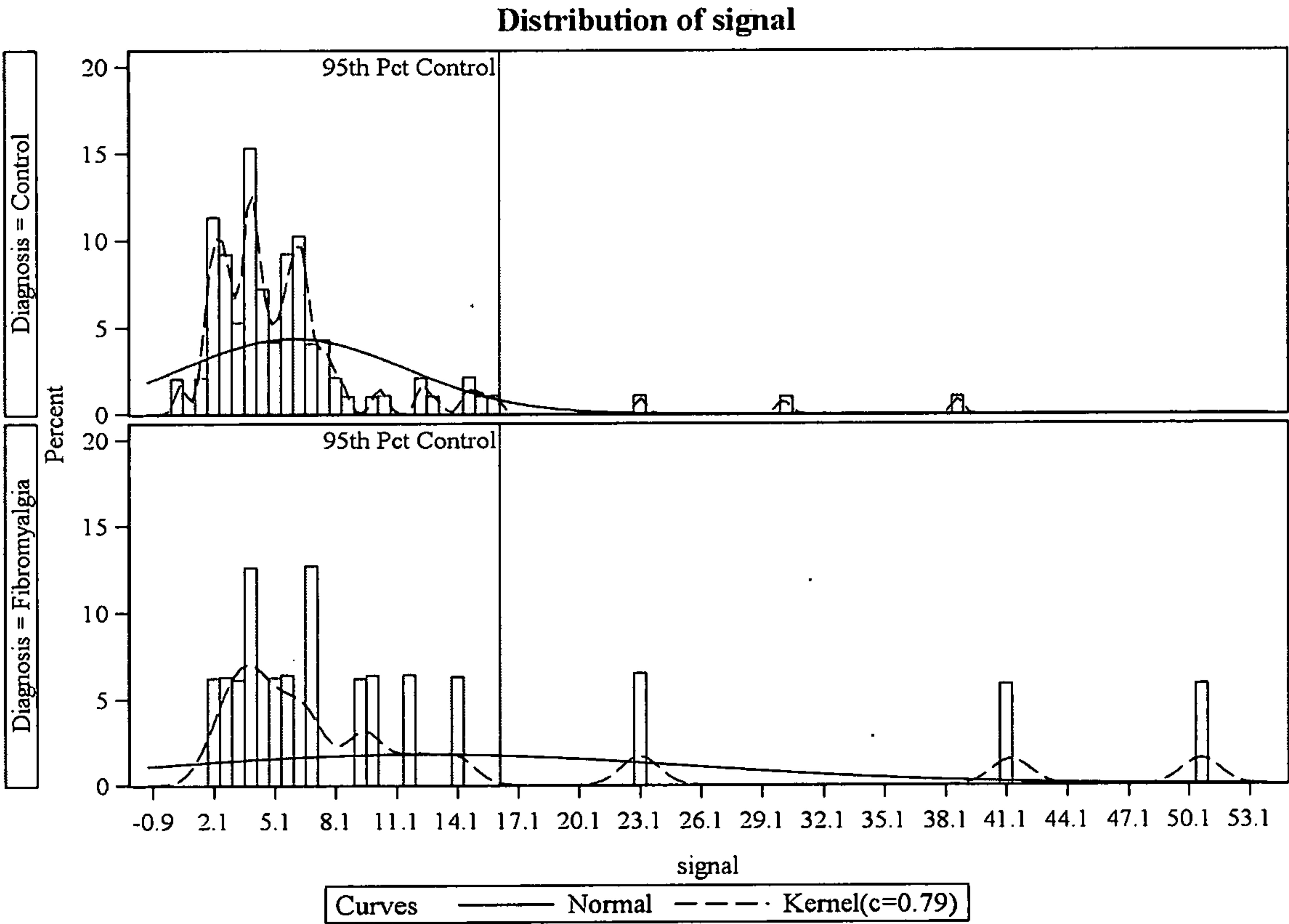


Figure 3A

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples
Sex=MALE Food=Cantaloupe***

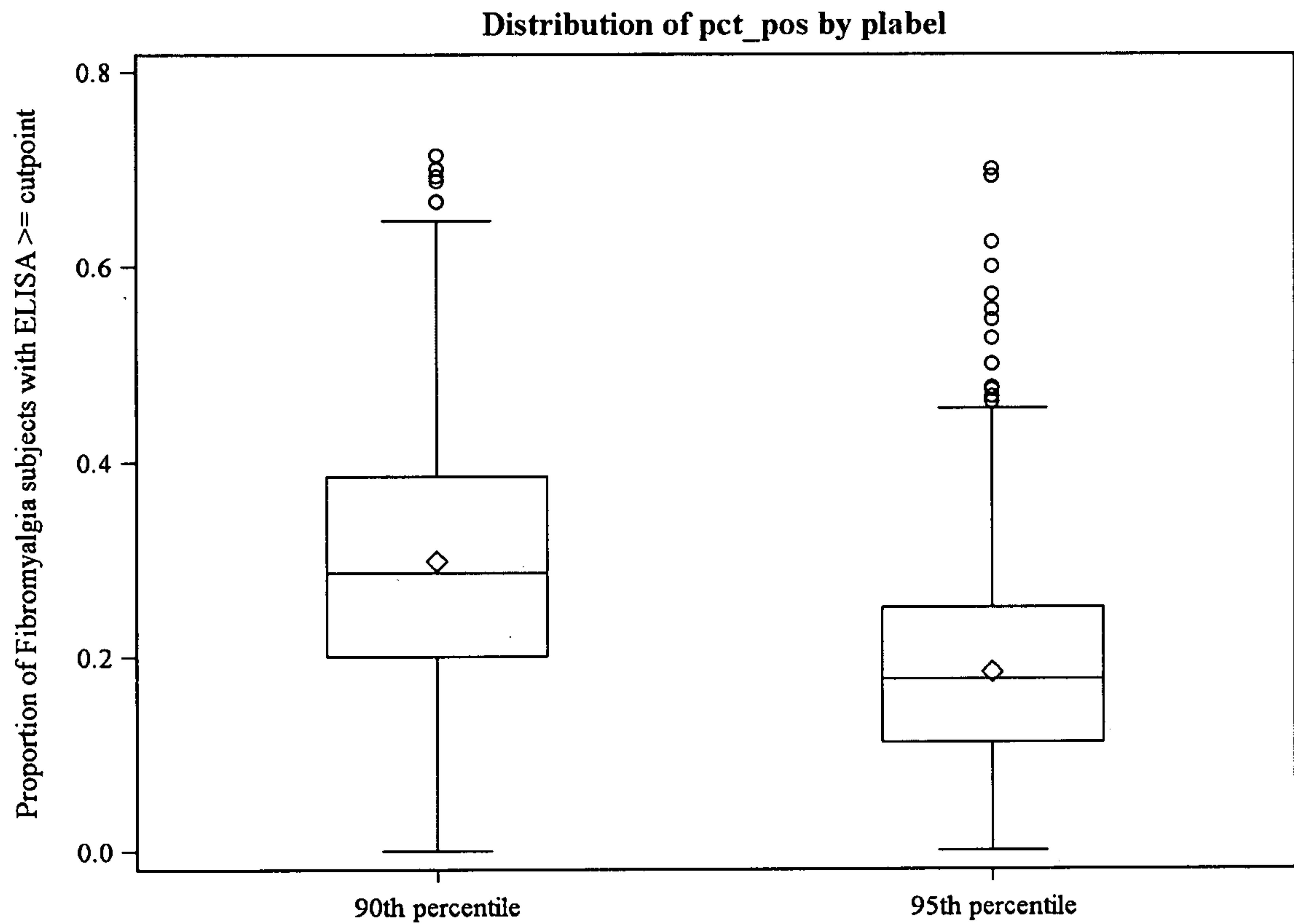


Figure 3B

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

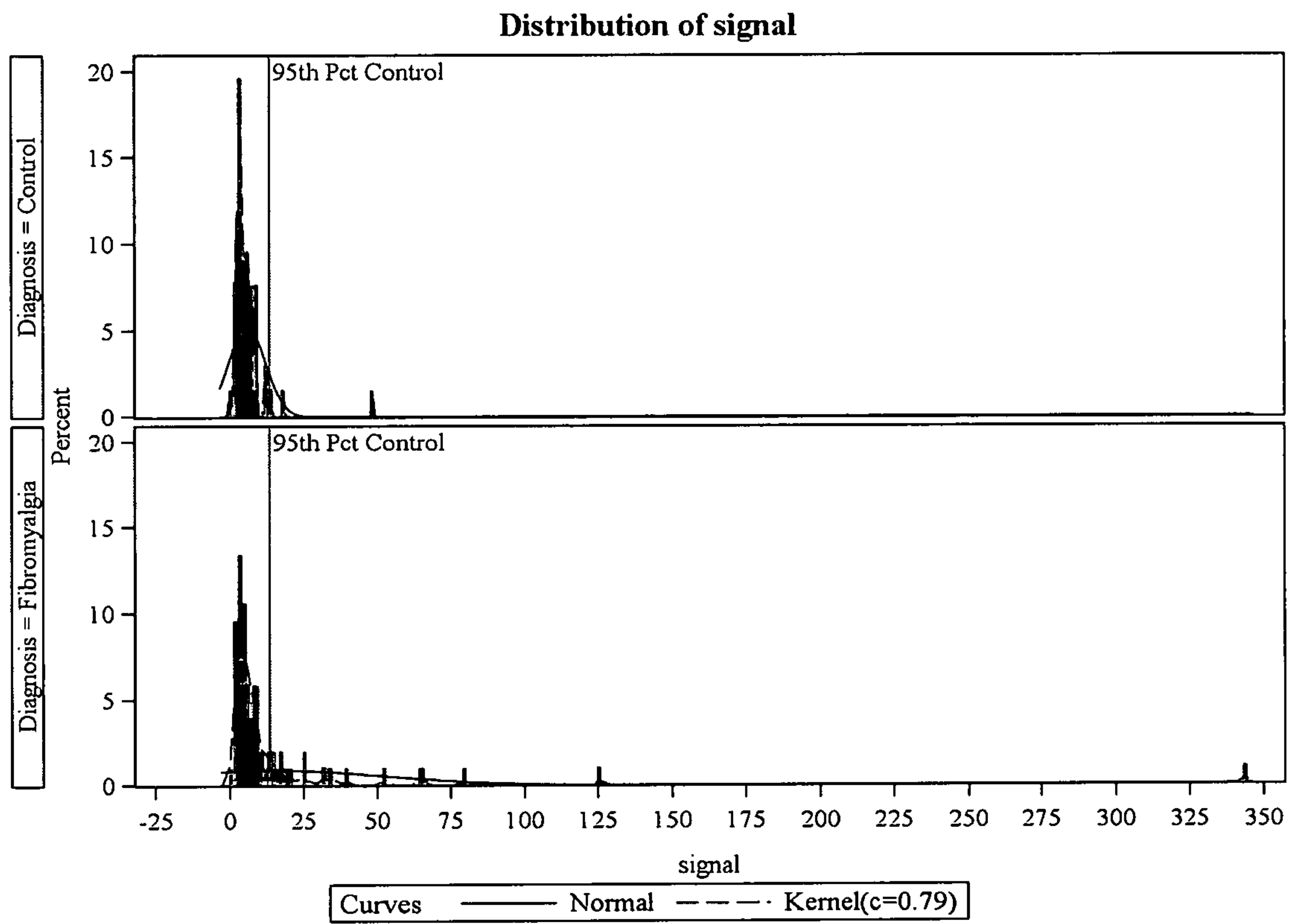


Figure 3C

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples***

Sex=FEMALE Food=Cantaloupe

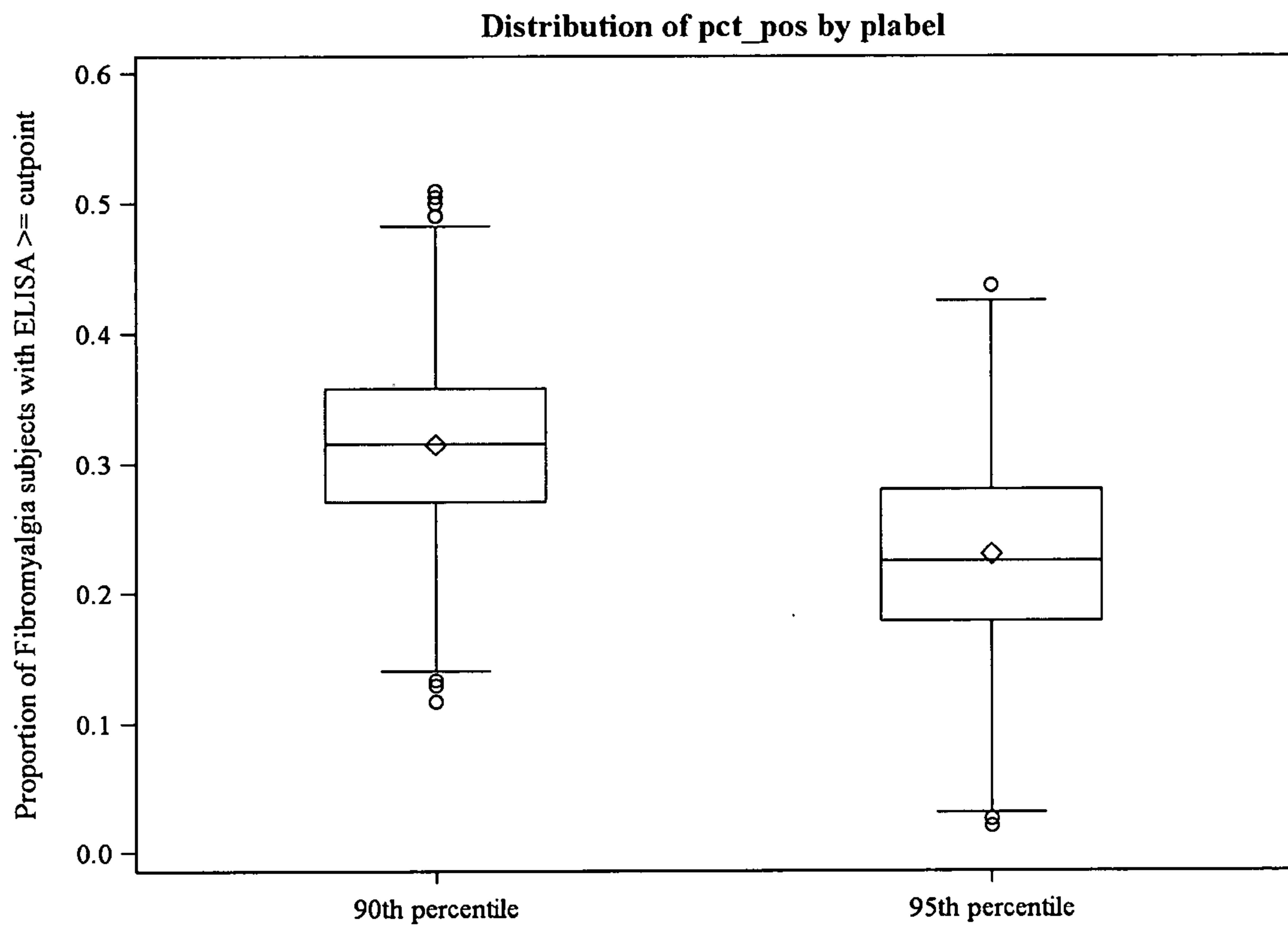
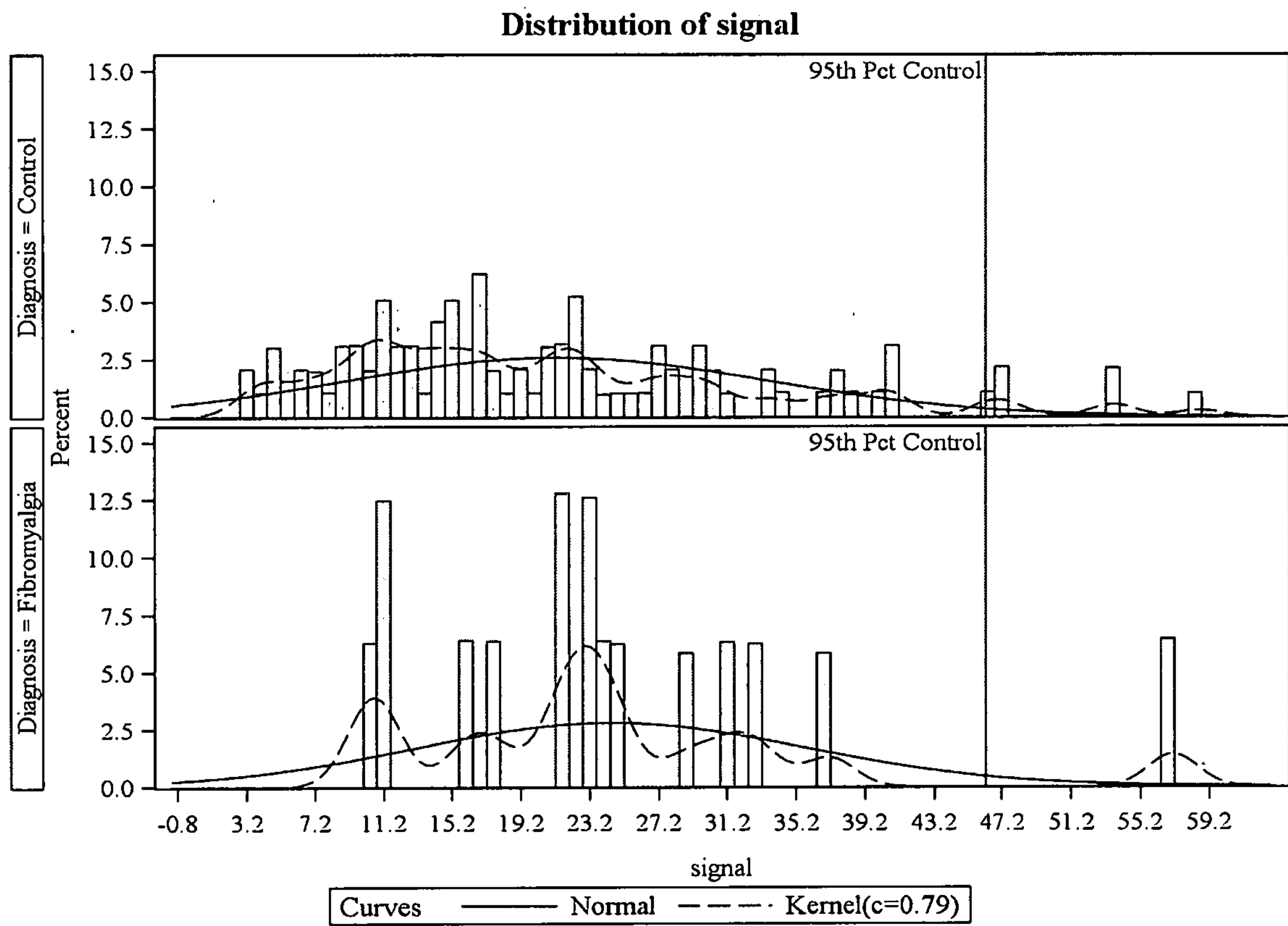


Figure 3D

*Distribution of ELISA Signal Scores by Diagnosis**Sex=MALE Food=Malt***Figure 4A**

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples
Sex=MALE Food=Malt***

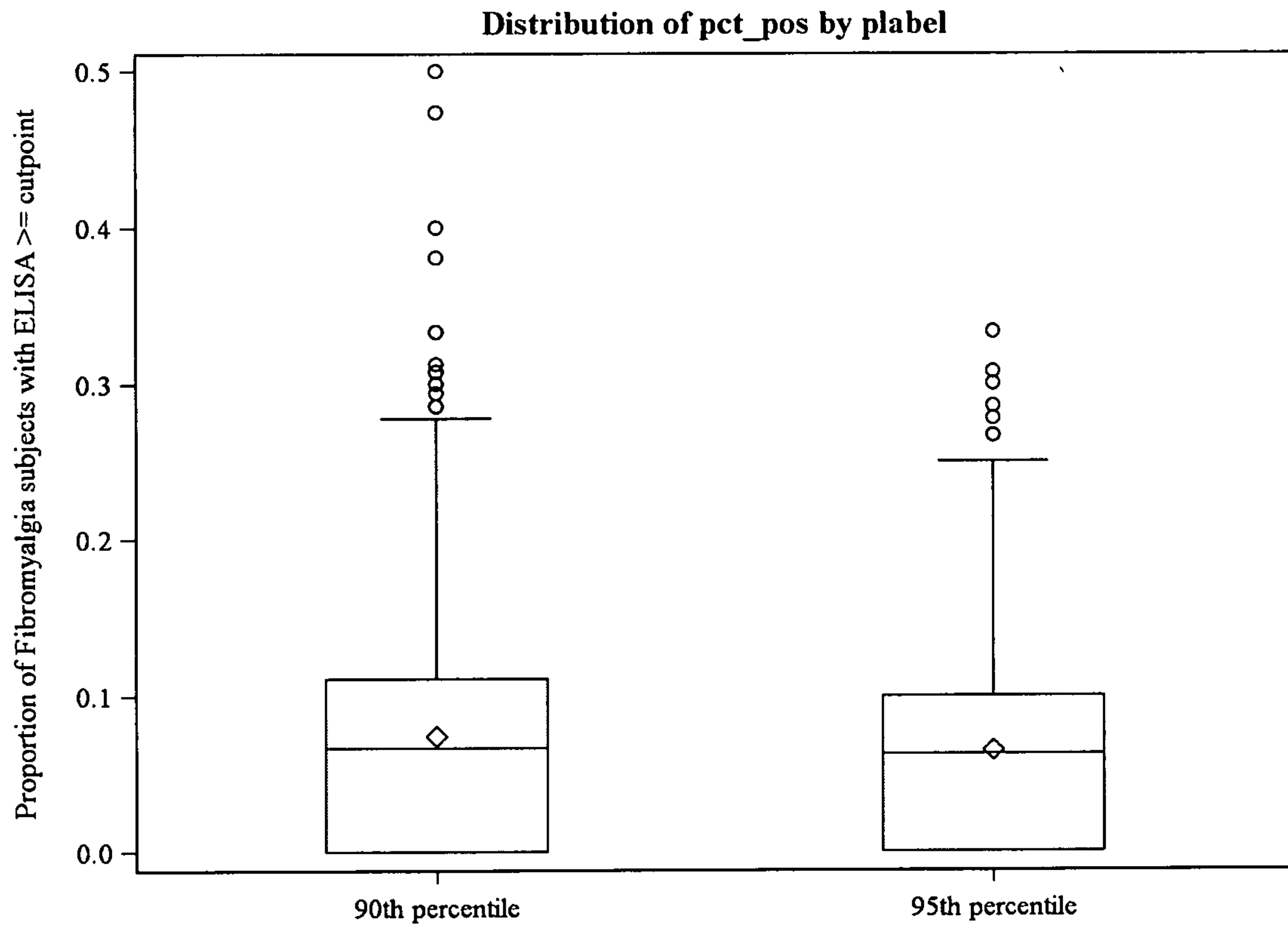


Figure 4B

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

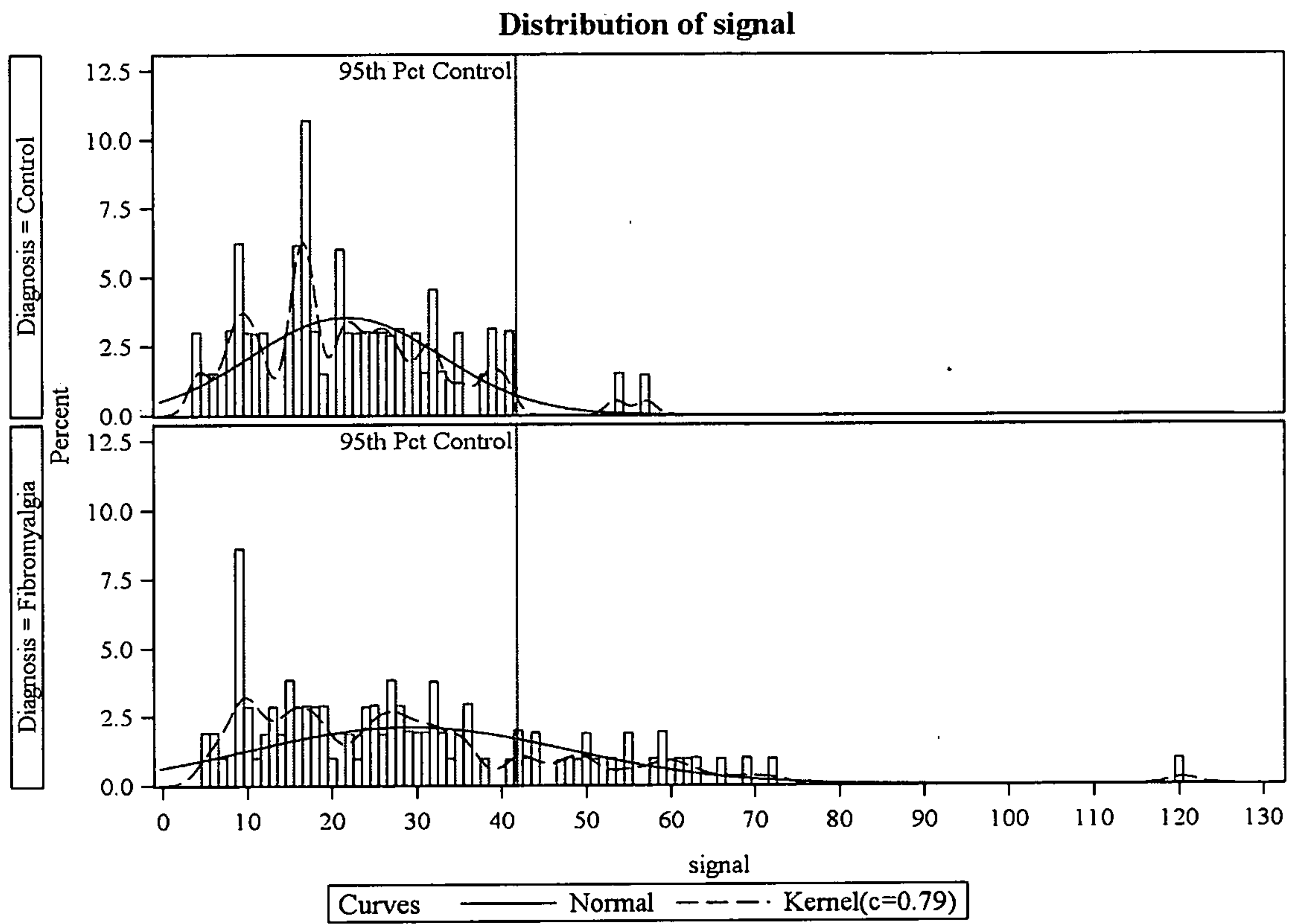


Figure 4C

***Distribution of Percentage of Fibromyalgia Subjects with Signals $\geq$ Control
Cutpoint across 1000 Bootstrapped Samples
Sex=FEMALE Food=Malt***

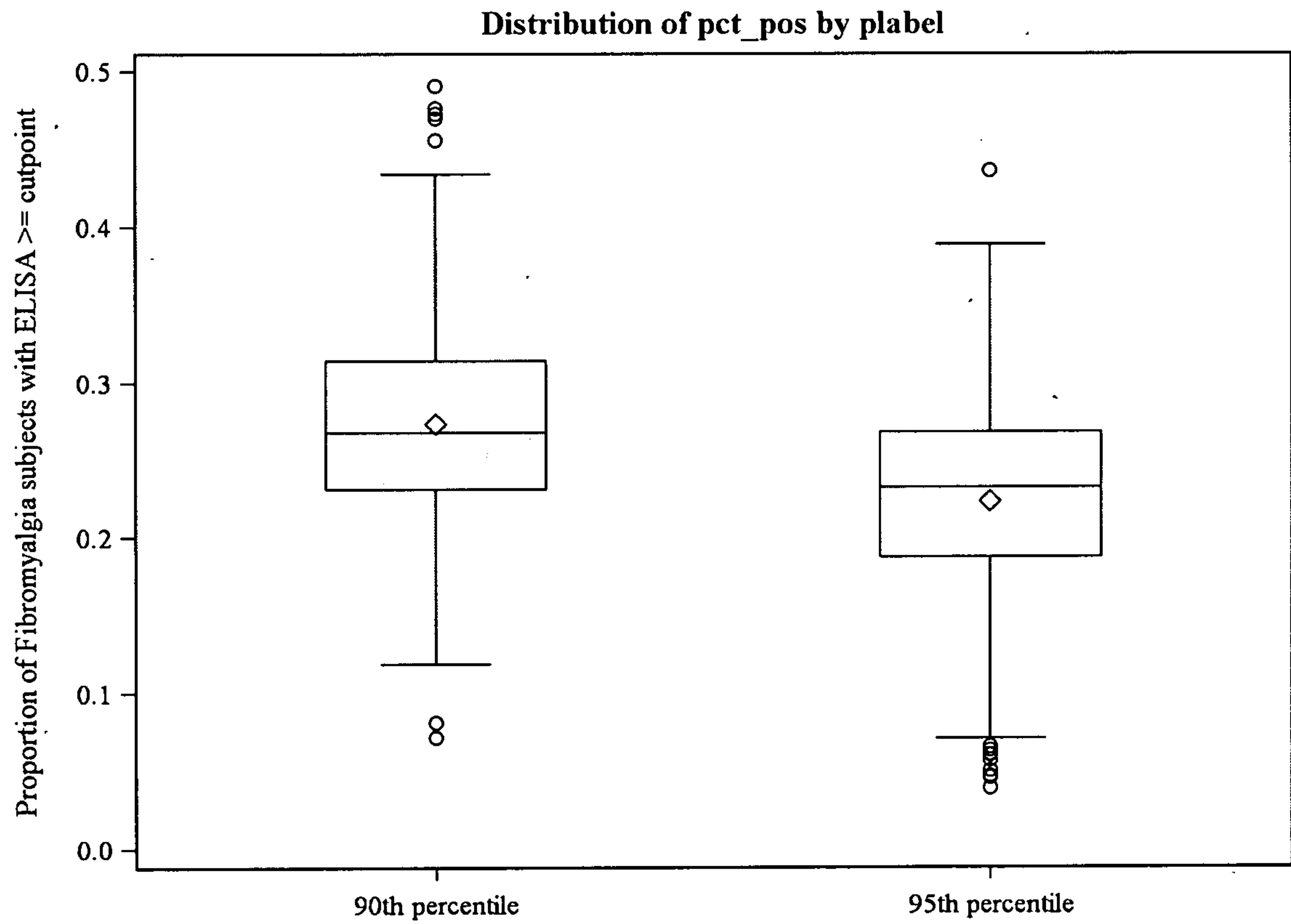


Figure 4D

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

90th Percentile as Cutpoint

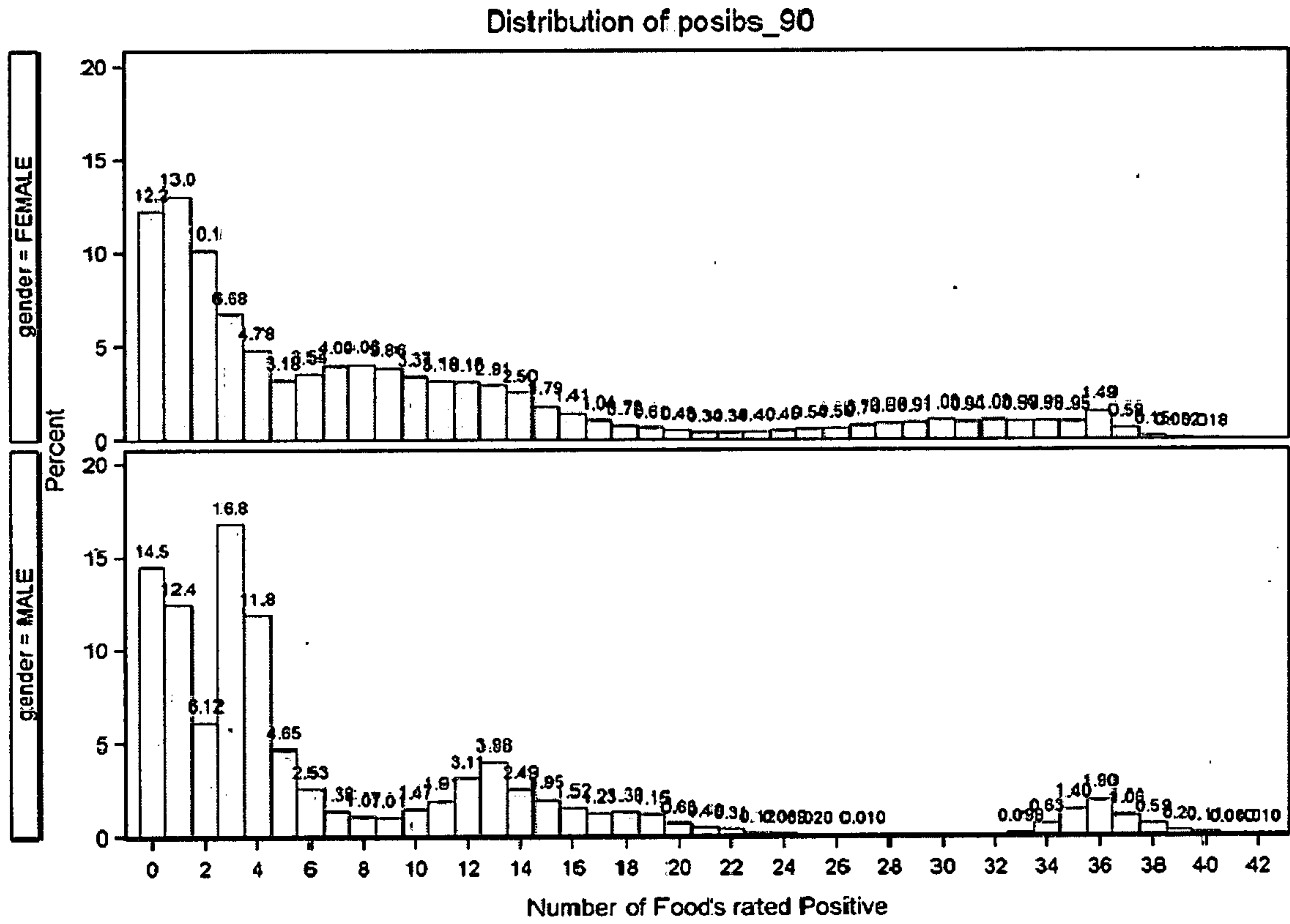


Figure 5A

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

95th Percentile as Cutpoint

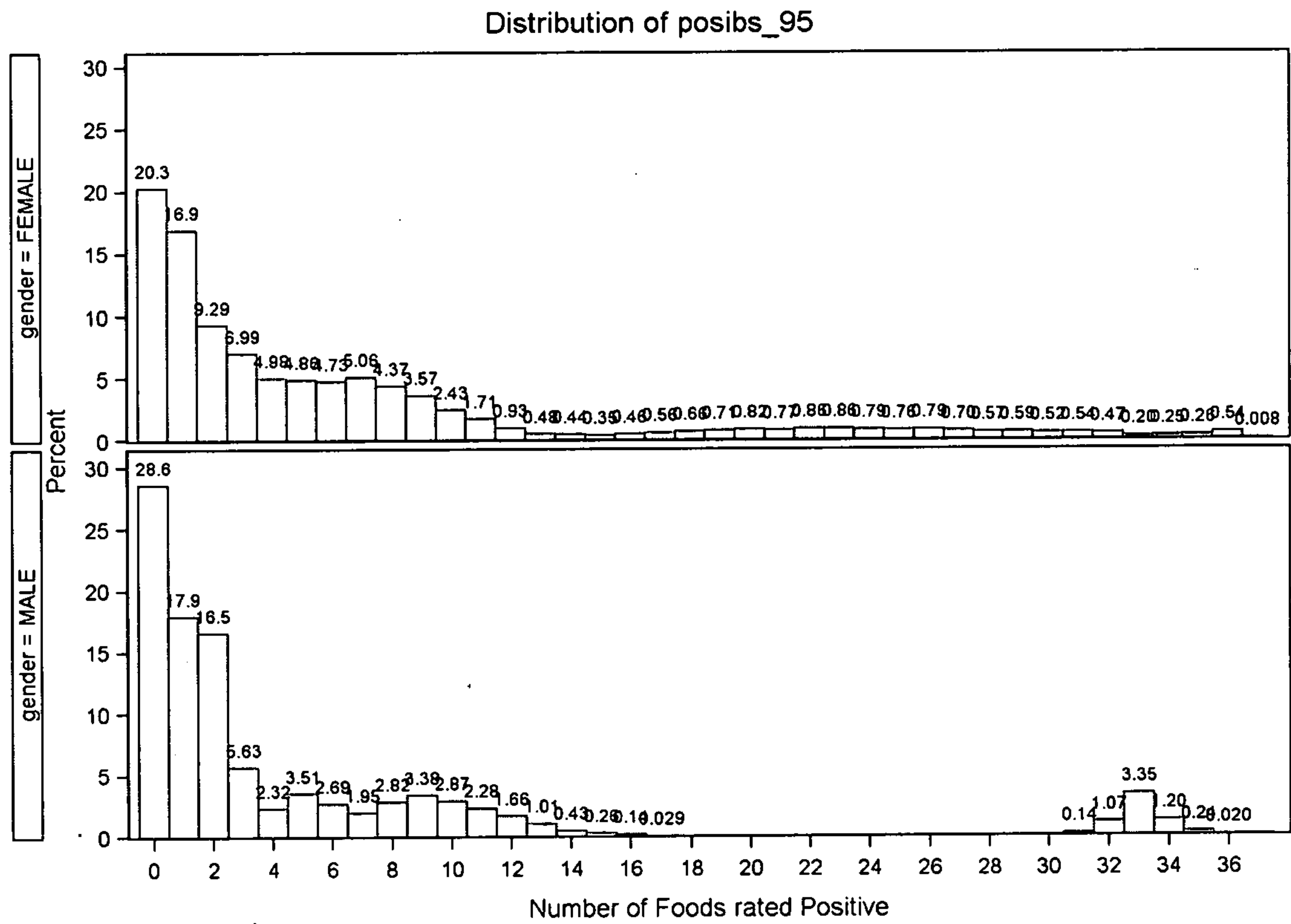
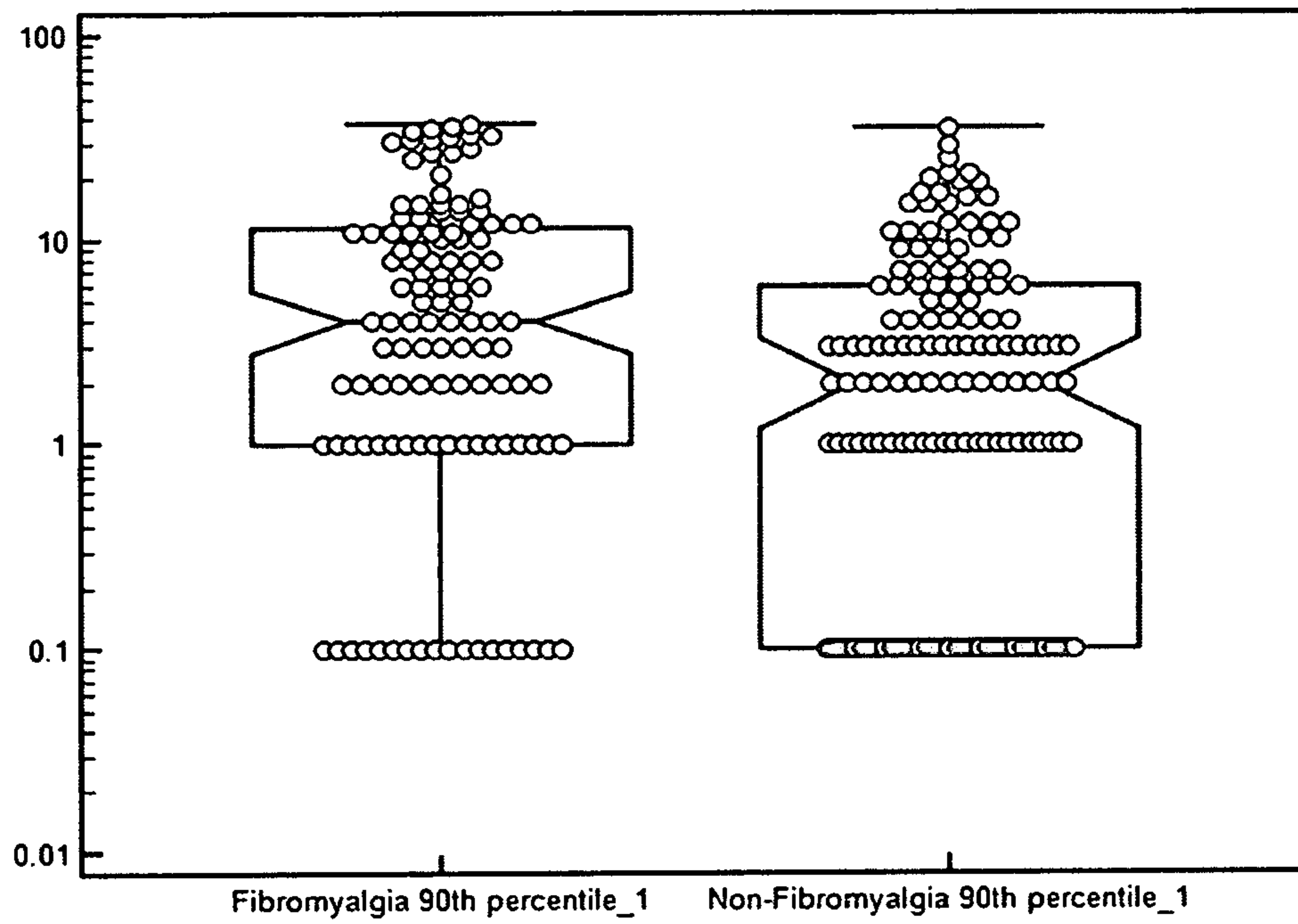
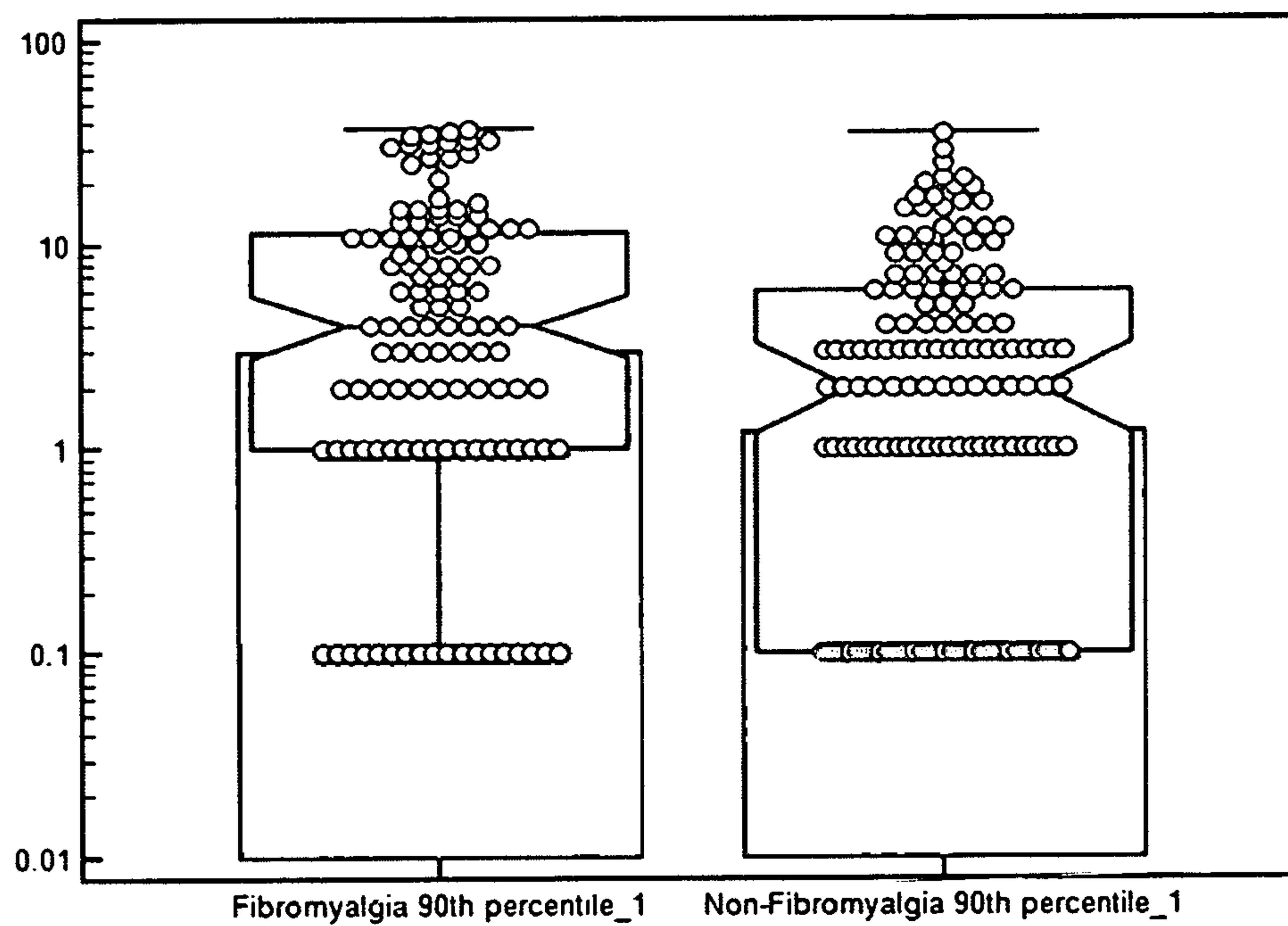


Figure 5B

**Figure 6A****Figure 6B**

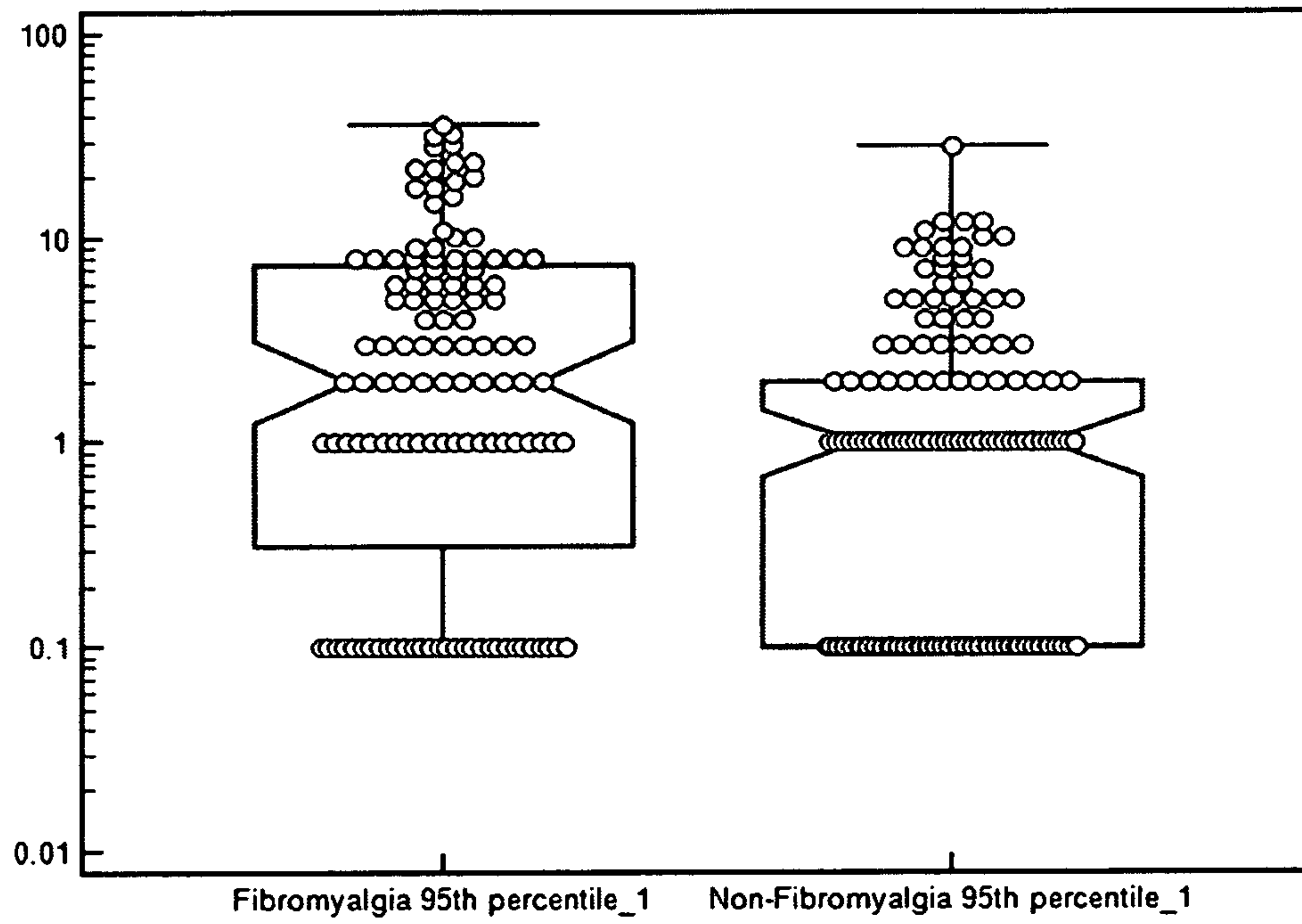


Figure 6C

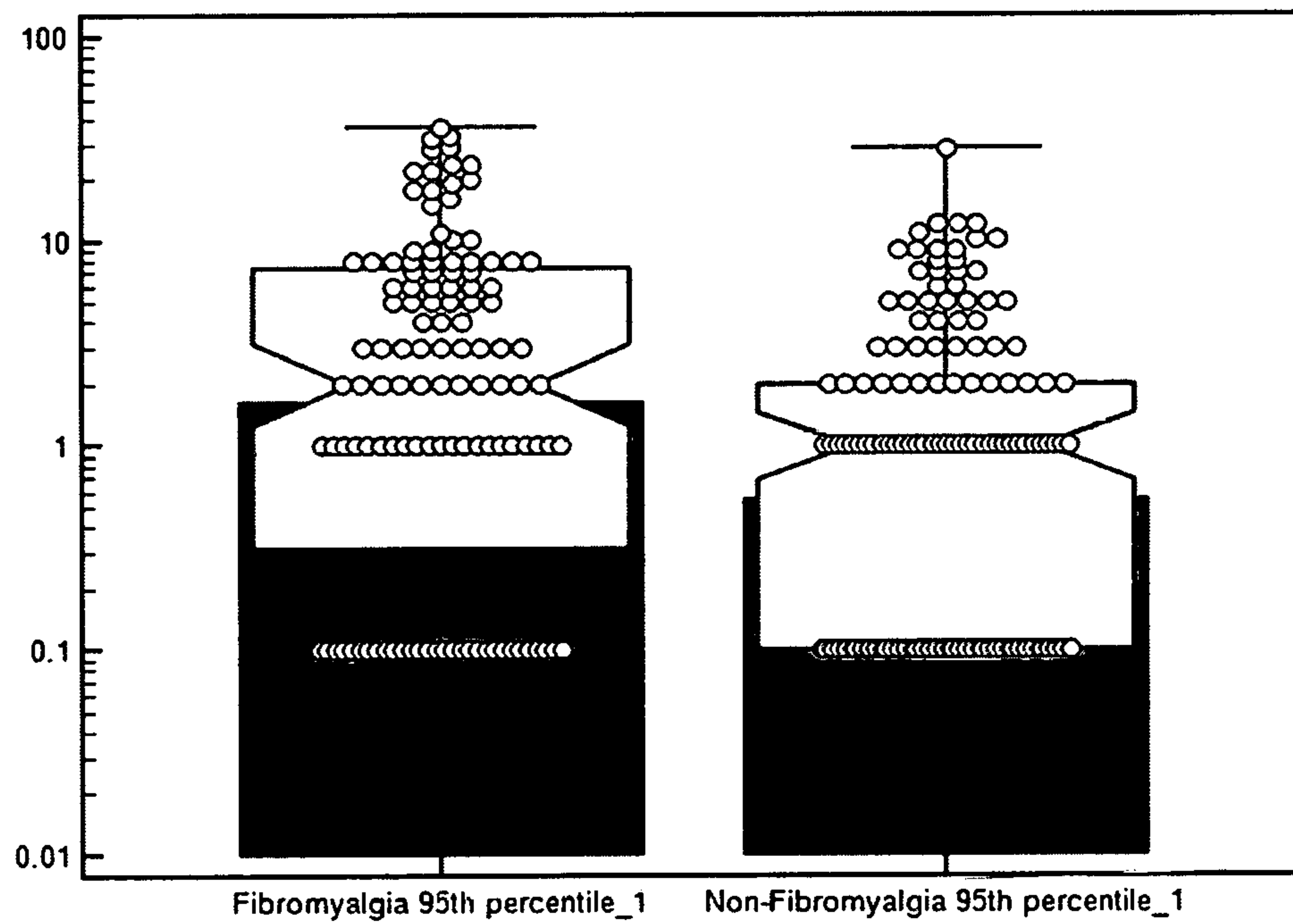
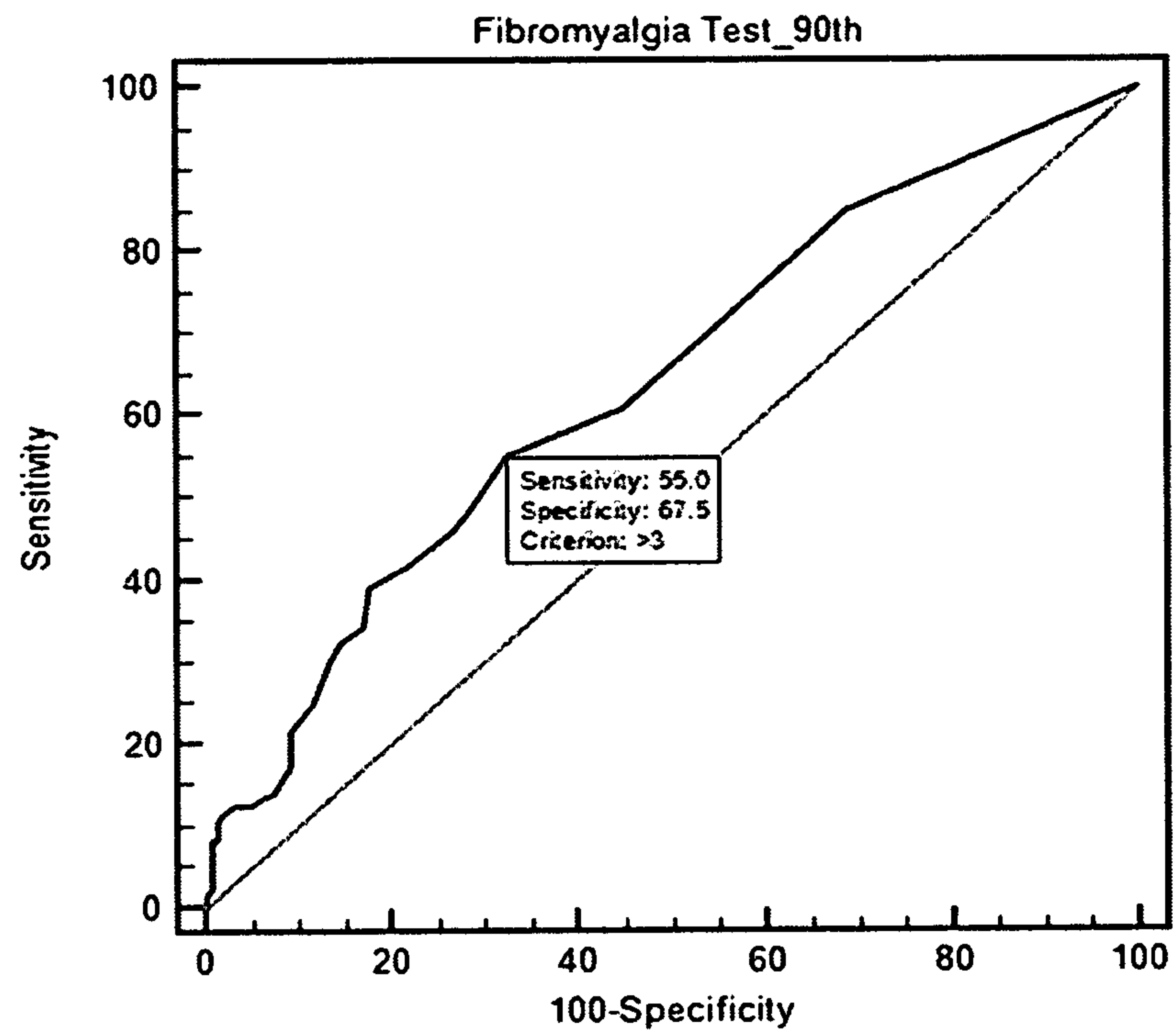
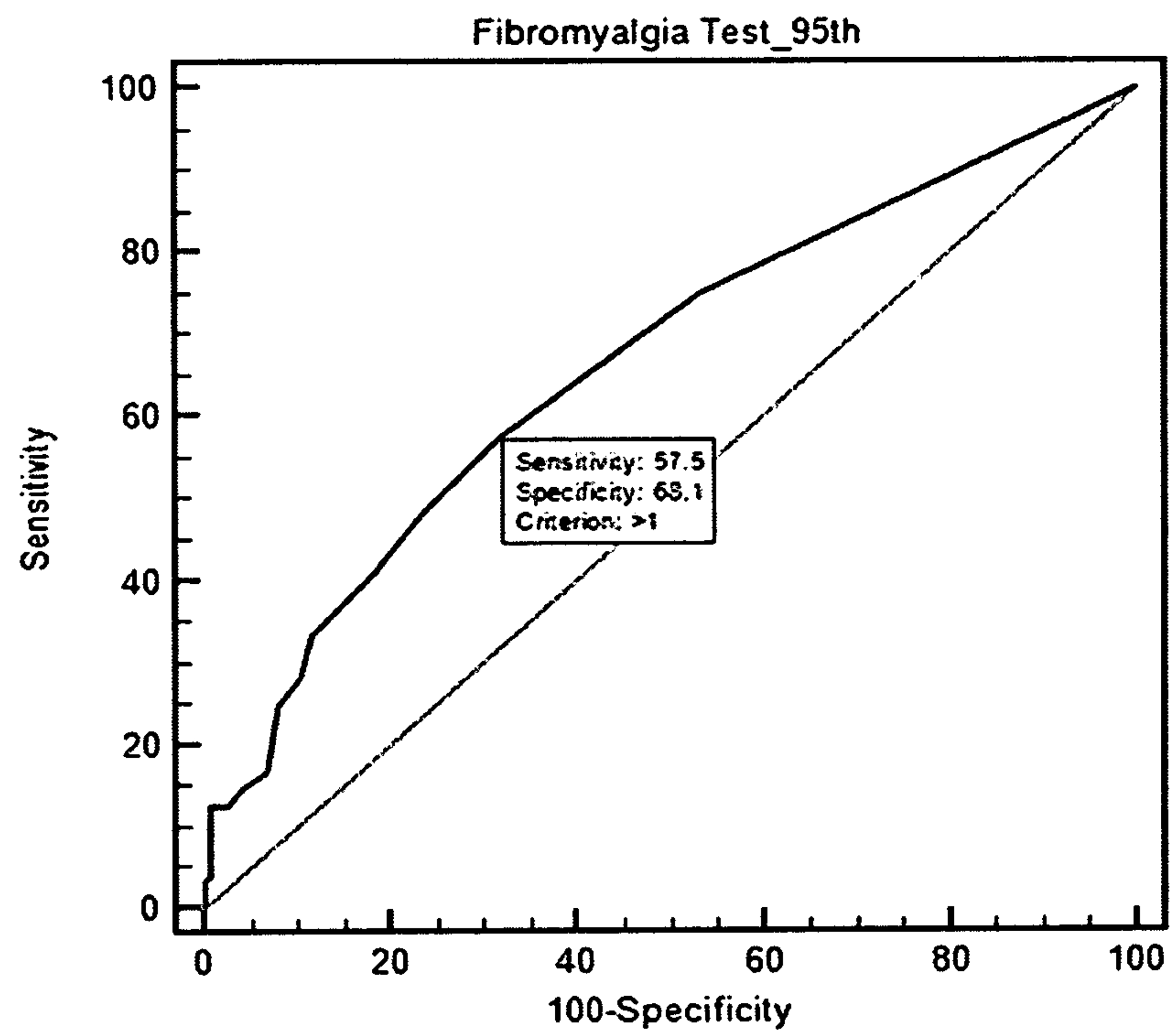


Figure 6D

**Figure 7A**

**Figure 7B**

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

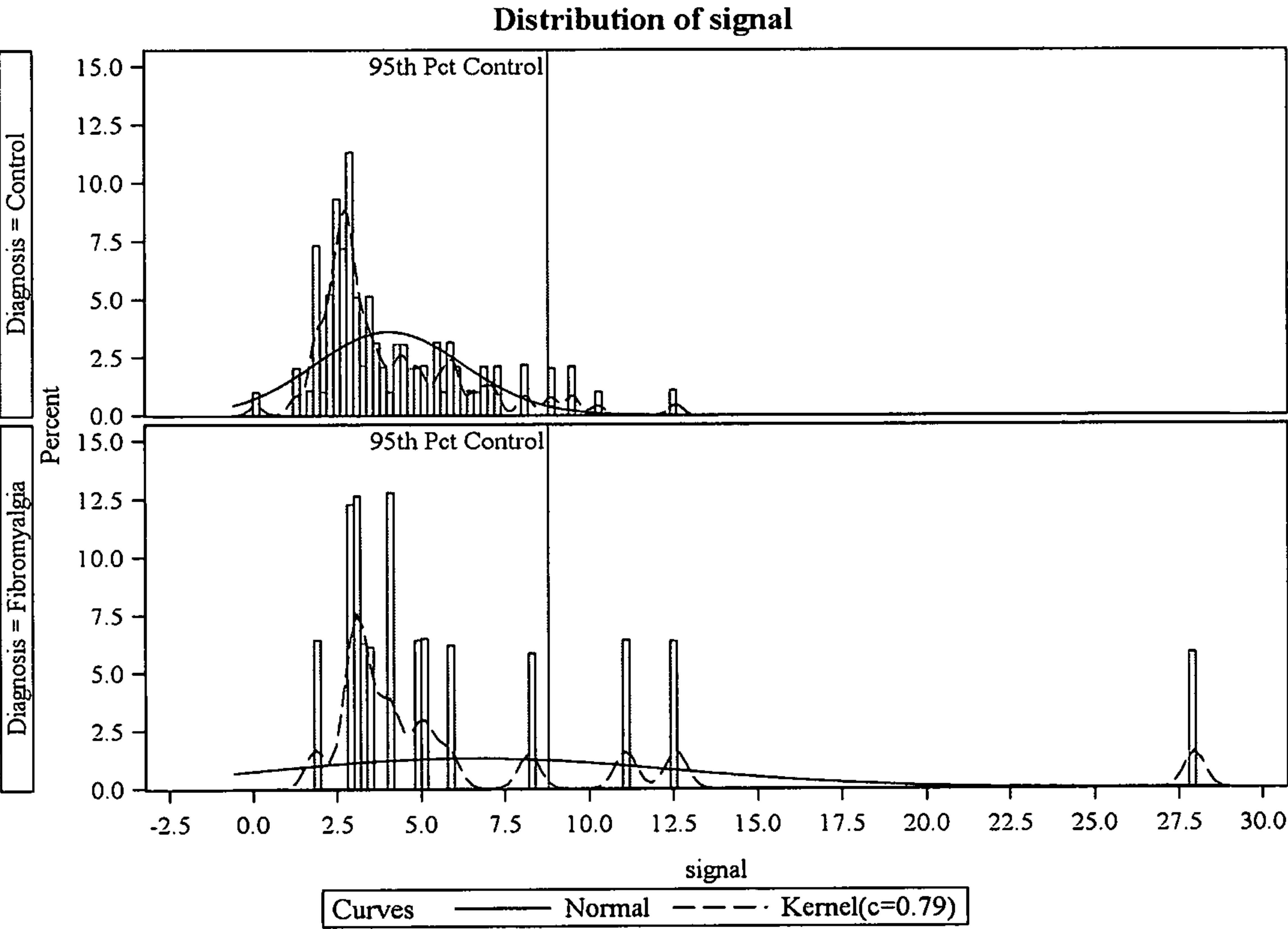


Figure 1A