K082205

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IN USA 800.233.1843
TEL 262.754.1000
FAX 262.754.9831
EMAIL gti@gtidiagnostics.com
WWW gtidiagnostics.com

20925 Crossroads Circle, Suite 200
Waukesha, WI 53186 USA

510(k) Summary

I. Submitter:

Owner's Name:	Genetic Testing Institute, Inc. (GTI)
Address:	20925 Crossroads Circle Suite 200, Waukesha, WI 53186
Phone:	262.754.1000
Fax:	262.754.9831
Name of Contact Person:	Michelle A. Stapleton, Ph.D.
Date Summary Prepared:	June 24, 2008

II. Name of Device:

Device Name:	Factor VIII Antibody Screen
Common Name:	ELISA for Factor VIII Antibody Detection
Classification Name:	Test, Qualitative And Quantitative Factor Deficiency
Product Code:	GGP

III. Name of predicate device for claiming equivalence

GTI Factor VIII Inhibitor Assay (K993553)

IV. Description of Device:

The Factor VIII Antibody Screen is an Enzyme Linked Immunosorbent Assay with a colorimetric endpoint. The Factor VIII Antibody Screen is designed to detect IgG antibodies reactive with recombinant human Factor VIII in human serum and plasma. The Factor VIII Antibody Screen kit contains all of the reagents necessary to perform the assay.

One of the most detrimental complications observed in the treatment of hemophilia A is the development of antibodies to FVIII. These antibodies can be either inhibitory or non-inhibitory in regards to FVIII activity. The presence of inhibitory antibodies may lead to the direct neutralization of transfused or endogenous FVIII activity. The non-inhibitory antibodies may lead to increased clearance of FVIII from circulation in an antibody mediated manner or by preventing the FVIII from binding to its carrier protein, von Willebrand Factor. Antibodies to Factor VIII are also present in patients with acquired hemophilia.

The Factor VIII Antibody Screen solid phase ELISA microwells provide immobilized recombinant human FVIII as target molecules for the detection of anti-Factor VIII IgG antibodies.

Diluted patient serum or plasma is added to microwells coated with recombinant FVIII molecules allowing antibody, if present, to bind. Unbound material is then washed away. An alkaline phosphatase labeled anti-human immunoglobulin reagent (Anti-IgG) is added to the wells and incubated. The unbound Anti-IgG is washed away and the substrate PNPP (p-nitrophenyl phosphate) is added. After a 30 minute incubation period, the reaction is stopped by a sodium hydroxide solution. The optical density of the color that develops is measured in a spectrophotometer at 405 nm with no reference filter.

V. Intended Use

The Factor VIII Antibody screen is a qualitative solid phase enzyme linked immunosorbent assay (ELISA) designed to detect IgG antibodies reactive with recombinant human factor VIII (FVIII) in human serum and plasma.

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VI. Support of substantial equivalence based on comparison of features, characteristics and components to the predicate device:

A comparison of the features and characteristics of the two devices can be summarized as follows:

	Factor VIII Inhibitor Assay	**Factor VIII Antibody Screen**
Intended Use	The Factor VIII Inhibitor Assay is a solid phase enzyme linked immunosorbent assay (ELISA) designed to detect IgG antibodies reactive with recombinant human factor VIII.	The Factor VIII Antibody Screen is a qualitative solid phase enzyme linked immunosorbent assay (ELISA) designed to detect IgG antibodies reactive with recombinant human factor VIII (FVIII) in human serum and plasma.
Indications for Use	The GTI-FVIII Inhibitor Assay is designed as a solid phase Enzyme-Linked Immunosorbent Assay (ELISA). The product is intended to be used as an in vitro diagnostic kit by hemostasis and other laboratories providing factor VIII inhibitor assay to assist in screening samples for the presence of alloantibodies to epitopes on the FVIII molecule.	The Factor VIII Antibody Screen is designed as a solid phase enzyme-linked immunosorbent assay (ELISA) with a colorimetric endpoint. This product is intended to be used as an in vitro diagnostic kit by hemostasis and other laboratories to screen patient samples for the presence of IgG antibodies reactive with human FVIII.
Technology	ELISA with a colorimetric endpoint	ELISA with a colorimetric endpoint
Reportable Results	Qualitative assay; results are reported as positive or negative	Qualitative assay; results are reported as positive or negative

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Interpretation of Test Results	Samples with average OD values greater than or equal to twice (2x) the average OD value of the negative control are positive. Samples with average OD values less than twice (2x) the average OD value of the negative control are negative.	Samples with average OD values greater than the average OD value of the kit control are positive. Samples with average OD values less than or equal to the average OD value of the kit control are negative.
Packaging Configuration	6 to 45 tests per kit	6 to 44 tests per kit
Sample Matrix	plasma collected in ACD or 3.2% sodium citrate	plasma collected in ACD or sodium citrate and serum
Reagents		
Microwell Strips	Immobilized recombinant FVIII in starwell microwells	Immobilized recombinant FVIII in low-volume, flat bottom microwells
Source of Antigen	Recombinante (recombinant full-length human FVIII stabilized with human serum albumin)	Kogenate FS (recombinant full-length human FVIII stabilized with sucrose)
Concentrated Wash Solution	10X Tris Buffer, NaCl, Tween 20, 1% NaN_3	10X Tris Buffer, NaCl, Tween 20, 1% NaN_3
Specimen Diluent	Tris buffered solution containing sodium choride and 0.05% NaN_3	Tris buffered solution containing sodium choride and 0.05% NaN_3 and 5% bovine serum albumin
Substrate Buffer	Diethanolamine and magnesium chloride, 0.02% NaN_3	Diethanolamine and magnesium chloride, 0.02% NaN_3
Substrate	PNPP (crystalline powder)	PNPP (crystalline powder)
Stopping Solution	3 M NaOH	3 M NaOH
Positive Control	Human serum containing antibodies to human FVIII in bovine albumin and 0.1% NaN_3	Human serum containing antibodies to human FVIII in bovine albumin and 0.1% NaN_3

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Kit Control	None	Human serum containing antibodies to human FVIII in bovine albumin and 0.1% NaN_3
Negative Control	Normal (from non-hemophilia donors) human serum containing 0.1% NaN_3	Normal (from non-hemophilia donors) human serum containing 0.1% NaN_3
Conjugate	Goat anti-human IgG conjugated to alkaline phosphatase enzyme	Goat anti-human IgG conjugated to alkaline phosphatase enzyme

The similarities between these two devices can be summarized as follows:

- Both the Factor VIII Inhibitor Assay and the Factor VIII Antibody Screen have similar intended uses and the similar indications for use.
- Both the Factor VIII Inhibitor Assay and the Factor VIII Antibody Screen use the same technology (ELISA with a colorimetric endpoint) and the same general assay steps.
- Both the Factor VIII Inhibitor Assay and the Factor VIII Antibody Screen use identical reagents with the exception of the microwell plates, specimen diluent, and kit control.

The difference between the two devices can be summarized as follows:

- The microwells for the Factor VIII Inhibitor Assay use starwells with immobilized Recombinate as the source of Factor VIII. The microwells are blocked with bovine serum albumin and coated with a stabilizing agent. The microwell plates for the Factor VIII Antibody Screen use low-volume, flat bottom microwells with immobilized Kogenate FS as the source of Factor VIII. The microwells for the Factor VIII Antibody Screen are not blocked with bovine serum albumin and are coated with the same stabilizing agent as the Factor VIII Inhibitor Assay.
- The Factor VIII Inhibitor Assay uses a Tris buffered solution containing sodium chloride and 0.05% sodium azide as the specimen diluent. The Factor VIII Antibody Screen uses a Tris buffered solution containing sodium chloride and 0.05% sodium azide with 5% bovine serum albumin as the specimen diluent.
- The Factor VIII Inhibitor Assay uses the negative control to determine the cutoff for positive samples. Any sample with an average optical density (OD) value greater than or equal to

twice (2x) the average OD value of the negative control is positive. Any sample with an average OD value less than twice (2x) the average OD value of the negative control is negative. The Factor VIII Antibody Screen uses the kit control to determine the cutoff for positive samples. Any sample with an average OD value greater than the average OD value of the kit control is positive. Any sample with an average OD value less than or equal to the average OD value of the kit control is negative.

VII. Support of substantial equivalence based on performance data:

The details of each of the following studies are coved in Section 7: Performance Data of this 510(k). Only a brief summary of these studies is provided in this section.

Factor VIII Antibody Screen Assay Cutoff

Description of Study

Since there is no internationally accepted standard for measurement of anti-FVIII antibodies, GTI developed its own standardization system and material used for the determination of the assay cutoff. In the Factor VIII Antibody Screen, the cutoff value used to assign a reportable result (positive or negative) to a patient sample is set by the kit control. Any sample with an average OD value > than the average OD value of the kit control is positive. Any sample with an average OD value $\leq$ the average OD value of the kit control is negative. The appropriate value for the kit control was determined by analysis of samples from normal, healthy, non-hemophiliacs and samples from patients known to contain antibodies to FVIII. A cutoff which best distinguishes between the two populations was chosen.

The kit control is a diluted serum known to contain antibodies to Factor VIII. The dilution chosen to make the kit control is lot specific and is determined based on the specific reactivity of each kit lot. Each time a kit lot is manufactured, all of the reagents are produced prior to the manufacture of the kit control. The reagents assigned to that particular kit lot are used in determining the best serum dilution to make the kit control. Testing includes assaying 78 different serum samples from normal, healthy, non-hemophilic donors and 3 known positive samples with low reactivity. The 3 positive samples and 78 normal samples are tested side-by-side with FVIII antibody positive serum diluted to various OD values. The average OD value for the 78 normal samples is calculated. A target value for the kit control is then chosen to be three times (3x) the average OD value of the normal samples. A dilution of the FVIII antibody positive serum is chosen such that it matches the target OD within 0.020 (+/-). The dilution which best matches the target value is used to manufacture the kit control. In addition to matching the target OD value, the chosen serum dilution must also yield the expected reportable results (positive or negative) for the samples tested. The 3 known positive samples with low reactivity must be positive and >98% of the normal samples must be negative.

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Qualification of Sample Type

Description of Study

In the method comparison study, described in this submission, samples collected as serum, plasma samples collected in ACD, plasma samples collected in 3.2% or 3.8% sodium citrate, and samples collected as plasma and converted to serum were included. For some sample types only small numbers of samples were available. The purpose of this study was to collect data further supporting the use of various sample types in the Factor VIII Antibody Screen. The unmodified Factor VIII Inhibitor Assay only allowed for plasma collected in ACD (acid citrate dextrose) or 3.2% sodium citrate to be used in the assay.

The effect of the different sample matrices were investigated in a series of experiments. First the FVIII Antibody Screen reportable results obtained from 3.2% sodium citrate plasma and serum drawn from the same 59 normal healthy, non-hemophiliacs were compared. Secondly, a three-way comparison testing samples collected from 14 healthy, non-hemophilia donors collected in serum, 3.2% sodium citrate, and ACD was conducted. Normal plasma samples from healthy, non-hemophiliacs were purchased as whole blood collected in 3.2% sodium citrate (blue-top) or ACD (yellow top) or were collected from GTI employees. Normal sera samples were collected from the same individuals into non-anticoagulated serum tubes (red-top).

In addition to normal samples, a study using spiked samples was conducted. Since we did not have access to the 3 sample types of interest collected from FVIII antibody positive patients, small amounts of Factor VIII antibody positive plasma were spiked into either 3.2% sodium citrate plasma and serum pairs drawn from normal, healthy, non-hemophiliacs or spiked into 3.2% sodium citrate plasma and ACD plasma pairs drawn from normal, healthy, non-hemophiliacs. The spiking was conducted such that the matrix was >90% serum or plasma (i.e. the lowest dilution was 1:10). The reportable results for each spiked sample pair were compared to determine if there was any significant difference in how the two sample matrices responded to the spike.

Results and Analysis

Samples from 59 normal donors drawn as serum or as plasma in 3.2% sodium citrate gave negative reportable results regardless of the sample matrix. In a three way comparison of serum, 3.2% sodium citrate plasma, and ACD plasma, samples from 14 normal donors gave negative reportable results regardless of the sample matrix. When antibody positive plasma was spiked into serum and 3.2% sodium citrate plasma pairs, all spiked samples yielded the same reportable result, regardless of the sample matrix. A total of 12 plasma and serum pairs became positive in this experiment. When antibody positive plasma was spiked into 3.2% sodium citrate plasma and ACD plasma pairs, all spiked samples yielded the same reportable result, regardless of the sample matrix. A total of 24 plasma pairs became positive in this experiment.

Conclusions:

In this set of experiments, no difference was observed between the reportable results obtained from samples collected as 3.2% sodium citrate plasma, ACD plasma or as serum. Differences between average OD values were noticed however there was no correlation to a specific sample matrix. From this study it

can be concluded that for the Factor VIII Antibody Screen, either plasma collected in 3.2% sodium citrate or ACD or serum can be used as the sample source. The method comparison study additionally supports the use of these sample types in the FVIII Antibody Screen.

Factor VIII Antibody Screen Precision

Description of Study

In this study a total of 8 samples were tested in duplicate in the Factor VIII Antibody Screen in 10 separate assays according the Factor VIII Antibody Screen direction insert.

Results and Analysis

To obtain imprecision of the OD values, the data were analyzed by ANOVA. In addition, the reportable result (positive or negative) was analyzed for agreement within and between runs.

The calculations of imprecision for the OD values showed that the assay demonstrated $\leq$ 13% cv total imprecision for samples with OD values greater than 0.600 and $\leq$ 24% cv total imprecision for samples with OD values less than 0.600. In addition, the correct reportable result was obtained for each result of each assay. There was 100% agreement between all reportable results (within-run and between-run) for each sample tested.

Conclusions:

The Factor VIII Antibody Screen showed acceptable assay imprecision of the OD values as well as the reportable results.

Accuracy of the Factor VIII Antibody Screen

Accuracy was demonstrated by a study in which the Factor VIII Antibody Screen was compared to both the Factor VIII Inhibitor Assay and the Bethesda assay. The data is a combination of an internal study conducted at GTI and an external study conducted at the Special Coagulation Lab, Mayo Clinic, Rochester, MN.

Description of Study:

The sample set used for method comparison consisted of more than 200 samples. Samples were collected from hemophiliac donors without Factor VIII antibodies (negative Bethesda titers or a negative Bethesda Screen) and from hemophiliac donors with Factor VIII antibodies (positive Bethesda titers). Sample types included in this study were serum collected as serum, serum converted from plasma, plasma collected in sodium citrate (3.2% or 3.8%), and plasma collected in ACD.

Results and Analysis:

The results of both the internal and external method comparison study were combined. Analysis of the data was performed using 2x2 tables and the calculations for co-positivity, co-negativity, and % agreement are shown below.

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2x2 Table for Combined Method Comparison Between the FVIII Antibody Screen and the FVIII Inhibitor Assay.

Factor VIII Antibody Screen	Factor VIII Inhibitor Assay: Positive	Negative	Total
Positive	89	1	90
Negative	7	40	47
Total	96	41	137

% Agreement = 94.2%
Co-positivity = 92.7% **95% confidence interval (85.7 – 96.4%)**
Co-negativity = 97.6% **95% confidence interval (87.4 – 99.6%)**

2x2 Table for the Combined Internal and External Method Comparison Between the Factor VIII Antibody Screen and the Bethesda Assay.

Factor VIII Antibody Screen	Bethesda Assay: Positive	Negative	Total
Positive	92	12	104
Negative	4	98	102
Total	96	110	206

% Agreement = 92.2%
Co-positivity = 95.8% **95% confidence interval (89.8 – 98.4%)**
Co-negativity = 89.1% **95% confidence interval (81.9 – 93.6%)**

In the method comparison between the Factor VIII Inhibitor Assay and the Factor VIII Antibody Screen a total of 8 samples showed discordant results. One sample was positive on the FVIII Antibody Screen and negative on the Factor VIII Inhibitor Assay. The cause of this discrepancy remains unknown, however the sample was only tested once on the Factor VIII Inhibitor Assay. The other 7 discordant samples were positive on the FVIII Inhibitor Assay and negative on the FVIII Antibody Screen. These samples were from hemophiliac patients that had negative Bethesda titers or Bethesda Screen results and would not be expected to contain antibodies to Factor VIII. In the FVIII Inhibitor Assay, the reactivity of these samples was reduced in the presence of a diluent containing BSA, suggesting non-FVIII specific background binding, however the OD values were not reduced enough to give a negative reportable result in 5 of the 7 samples.

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In the method comparison between the Factor VIII Antibody Screen and the Bethesda assay, four Bethesda positive samples were missed on the FVIII Antibody Screen. These samples ranged in Bethesda titer from 0.8 to 3 with 0.8 being the cutoff for a positive Bethesda assay. The cause of these discrepancies remains unknown. Twelve samples that were assigned negative Bethesda reportable results were found to be positive on the Factor VIII Antibody Screen. In most cases, these samples were from patients which later developed an inhibitor or had been treated with immune tolerance to abrogate the inhibitor. It is believed that these discrepant samples indicate an increased sensitivity of the ELISA compared to the functional assay, possibly due to the fact that the ELISA can detect both inhibitory and non-inhibitory FVIII antibodies.

For comparison, a summary table of all both of the combined 2x2 table analyses is provided below:

	FVIII Antibody Screen vs. FVIII Inhibitor Assay	**FVIII Antibody Screen vs. Bethesda Assay**
Sensitivity (Co-positivity)	92.7%	95.8%
95% Confidence Interval	85.7 – 96.4%	89.8 – 98.4%
Specificity (Co-negativity)	97.6%	89.1%
95% Confidence Interval	87.4 – 99.6%	81.9 – 93.6%
% Agreement	94.2%	92.2%

Conclusions

The Factor VIII Antibody Screen showed excellent sensitivity (co-positivity), specificity (co-negativity), and overall agreement with the predicate device (Factor VIII Inhibitor Assay). In addition, the Factor VIII Antibody Screen showed excellent sensitivity (co-positivity), specificity (co-negativity), and overall agreement when compared to the Bethesda assay. The Bethesda assay is considered to be the gold standard for detection and quantitation of inhibitory antibodies to Factor VIII.

Investigation of Possible Interfering Substances or Sample Conditions

Drugs commonly used in the treatment of hemophilia and sample conditions common to coagulation samples were tested for possible interference in the Factor VIII Antibody Screen. The following provides a description of the study, the results, and conclusions. This study was conducted as an internal study at GTI.

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Description of Study

The purpose of this study was to look at common sample conditions seen in coagulation testing and determine if any of these conditions cause interference in the Factor VIII Antibody Screen. In addition, two substances often used in treatment of hemophilia, Gammagaurd (IVIG) and Rituxan (rituximab), were tested to determine if the presence of the drugs interfere with the assay results. This testing was conducted as a series of spiking experiments. The addition of hemoglobin was used to mimic hemolyzed samples, billirubin was used to mimic icteric samples, and intralipid was used to mimic lipemic samples. Three samples (1 negative, 1 with medium reactivity, and 1 with high reactivity) were tested with all possible interferences in replicates of 10.

Hemoglobin and Intralipid were tested at 500mg/dL in the sample and billirubin was tested at 20mg/dL in the sample. The Gammaguard (IVIG) was tested at a concentration of 200 µg/mL in the sample and Rituxan (rituximab) was tested at a concentration of 10 µg/mL in the sample.

Results and Analysis:

For the two positive samples tested, the % difference between the average OD values obtained in the presence or absence of the test compound is < 24% for all test compounds and the OD values were not consistently increased or decreased on the basis of the presence of the test compound. For the negative sample, the % difference between the average OD values obtained in the presence or absence of the test compound range up to 63%, however these OD values are less than 0.110 and this type of variation is expected. For all samples tested with all compounds tested, the reportable results were the same in the presence or absence of the test compound.

Conclusions:

The use of lipemic, icteric, or hemolyzed patient samples should not result in an incorrect test result with the Factor VIII Antibody Screen. The presence of IVIG up to 200 µg/mL or rituximab up to 10 µg/mL in a patient sample should not result in an incorrect test result with the Factor VIII Antibody Screen.

Factor VIII Antibody Screen Lot to Lot Reproducibility

Description of Study

The study consisted of testing a set of 12 samples in duplicate in 3 separate assays on 3 different kit lots. The sample set consisted of 7 known negative samples and 5 known positive samples.

Results and Analysis

All known positive samples gave positive reportable results in each assay run on all kit lots. All known negative samples gave negative reportable results in each assay run on all kit lots. There was 100% agreement between reportable results for all 3 kit lots.

Conclusions
Excellent lot to lot accuracy and reproducibility of the Factor VIII Antibody Screen was demonstrated in this study.

Stability Data to Support Expiration Dating

Description of Study:

The microwells, specimen diluent and kit control are the only components not used in the GTI Factor VIII Inhibitor Assay kit (predicate device). All reagents which are shared between the two kits have been assigned the shelf-life previously used in the Factor VIII Inhibitor Assay kits. The microwells used in the Factor VIII Antibody Screen are different enough from the microwells used in the Factor VIII Inhibitor Assay to warrant an accelerated stability study to determine a reasonable shelf-life. All other reagents are not sufficiently different from the reagents used in the GTI Factor VIII Inhibitor Assay to result in changes in reagent stability.

In addition to the accelerated stability study on the microwells, a real-time kit stability study is being conducted on a total of 3 kit lots.

Results and Analysis:

During the course of the accelerate microwell strip stability study, no time points constituted at failed assay. Therefore, there were no points of failure observed during this accelerated stability study. The microwell strips were stabile out to 20 weeks when stored at 40°C. Therefore the predicted shelf life of the microwell strips from this accelerated stability study would be 186 weeks (~3.5 years) when stored at 4°C (2-8°C). As with any accelerated stability study, the predicted shelf-life will be confirmed with a real-time stability study.

The results for the in-use and unopened kit stability study are very similar. For all samples tested at all time points the known negative sample gave negative reportable results and the known positive samples gave positive reportable results.

Conclusions:

To summarize, the data suggest that the new format microwell strips may be stable up to 3.5 years based on accelerated data. This dating will be confirmed with real-time stability results. The real-time stability studies are only out to 6 months and to date only include one kit lot. The kit has been shown to be stable at least for the 6 months completed in the study. This study is currently on-going and will be summarized in full in the final stability report for the Factor VIII Antibody Screen.

VIII. Conclusion

Based on comparison with the predicate device, (GTI Factor VIII Inhibitor Assay), these data demonstrate that the GTI Factor VIII Antibody Screen performs comparable to the predicate device and the Factor VIII Antibody Screen does not present new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Genetic Testing Institute
c/o Michelle A. Stapleton, Ph.D.
20925 Crossroads Circle Suite 200
Waukesha, Wisconsin 53186-4054

NOV 2 0 2008

Re: k082205
Trade/Device Name: Factor VIII Antibody Screen
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: Class II
Product Code: GGP
Dated: October 20, 2008
Received: October 23, 2008

Dear Dr. Stapleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Marian M Chan

Marian Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082205

Device Name: Factor VIII Antibody Screen

Indications for Use:

The Factor VIII Antibody Screen is designed as a solid phase enzyme-linked immunosorbent assay (ELISA) with a colorimetric endpoint. This product is intended to be used as an in vitro diagnostic kit by hemostasis and other laboratories to screen patient samples for the presence of IgG antibodies reactive with human Factor VIII.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K082205