October 10, 2025

Gold Standard Diagnostics, LLC.
Gerrit Mueller
Director, Product Management
2795 2nd St Ste 300
Davis, California 95618

Re: K250249
Trade/Device Name: Gold Standard Diagnostics (GSD) Rapid Plasma Reagin (RPR) Automated Test System
Regulation Number: 21 CFR 866.3820
Regulation Name: Treponema Pallidum Nontreponemal Test Reagents
Regulatory Class: Class II
Product Code: GMQ
Dated: September 10, 2025
Received: September 11, 2025

Dear Gerrit Mueller:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Himani Bisht -S

Himani Bisht, Ph.D.
Assistant Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250249

Device Name
Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System

Indications for Use *(Describe)*
The Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System is a non-treponemal flocculation test that can qualitatively determine the presence of reagin antibodies in human serum, automated on the AIX1000 Analyzer. It may be used to aid in the diagnosis of syphilis when used in conjunction with supplemental treponemal laboratory tests and other clinical information. This test may also be used to detect non-treponemal antibodies in samples serially diluted to establish titer information. This test is not intended for screening blood or tissue donors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

1) **Submitter's Name:** Gold Standard Diagnostics
   Address: 2795 2nd Street, Davis, CA. 95618
   Phone Number: 530-759-8000
   Contact Person: Gerrit Mueller
   Date: October 9, 2025

2) **Product and Trade Name:**
   Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System

   Common Name:
   Rapid Plasma Reagin (RPR) Test

   Regulation Section:
   (21 CFR 866.3820) Treponema pallidum non-treponemal test reagents.

   Classification:
   Class II

   Product Code:
   GMQ

3) **Legally Marketed Device to Which the Submitter Claims Equivalence:**
   Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System (K150358).

4) **Description of the Device:**
   The Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System in a non-treponemal test for the qualitative determination of reagin antibodies in human serum to aid in the diagnosis of syphilis. This test is also used to detect non-treponemal antibodies in samples serially diluted to establish titer information. The system consists of the Gold Standard Diagnostics RPR test reagents and the Gold Standard Diagnostics AIX1000 Agglutination Analyzer. The AIX1000 Analyzer delivers serum from collection tubes into test wells. After antigen suspension is added, the test wells are then incubated while being shaken. An onboard camera creates a high resolution image. The image is then analyzed by the proprietary software algorithm to produce a result.

The RPR test reagents consist of a reactive control, a non-reactive control, and the antigen suspended in a carbon solution. When the antigen is mixed with sera, if antibodies are present, they will bind to the antigen and form black flocculants due to the presence of carbon particles. If no antibodies are present, then the carbon particles remain evenly distributed.

The antigen used in the Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System is a modified VDRL carbon antigen. The formulation is the same as that established by the Center for Disease Control (CDC)[1] containing 0.03% cardiolipin, 0.9% cholesterol, and 0.21% lecithin.

The kit also includes untreated, 48 well reaction plates a reactive control and a non-reactive control.

[1] Kennedy, E.J. and Creighton, E.T. Venereal Disease Research Laboratory (VDRL) Slide Test. Syphilis Manual, Chapter 8. 1998. http://www.cdc.gov/std/syphilis/manual-1998/CHAPT8.pdf

5) Intended Use of the Device:

The Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System is a non-treponemal flocculation test that can qualitatively determine the presence of reagin antibodies in human serum, automated on the AIX1000 Analyzer. It may be used to aid in the diagnosis of syphilis when used in conjunction with supplemental treponemal laboratory tests and other clinical information. This test may also be used to detect non-treponemal antibodies in samples serially diluted to establish titer information. This test is not intended for screening blood or tissue donors.

6) Comparison with the Predicate Device:

The tables below provide a comparison of the Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma Reagin (RPR) Automated Test System (subject device: K250249) with the Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System (K150358).

Device & Predicate Device(s):	K250249	K150358
Device Trade Name	Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System	Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System
General Device Characteristics		
Intended Use/Indications For Use	The Gold Standard Diagnostics (GSD) AIX1000 Rapid Plasma	The Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin

	Reagin (RPR) Automated Test System is a non-treponemal flocculation test that can qualitatively determine the presence of reagin antibodies in human serum, automated on the AIX1000 Analyzer. It may be used to aid in the diagnosis of syphilis when used in conjunction with supplemental treponemal laboratory tests and other clinical information. This test may also be used to detect non-treponemal antibodies in samples serially diluted to establish titer information. This test is not intended for screening blood or tissue donors.	(RPR) Automated Test System is a non-treponemal flocculation test that can qualitatively determine the presence of reagin antibodies in human serum. It may be used to aid in the diagnosis of syphilis when used in conjunction with supplemental treponemal laboratory tests and other clinical information. This test may also be used to detect non-treponemal antibodies in samples serially diluted to establish titer information. This test is not intended for screening blood or tissue donors.
Assay Format	Reports qualitative results and titer of non-treponemal antibodies in serially diluted samples.	Same
Technology	Flocculation test	Same
Antigen	Modified VDRL carbon antigen	Same

Reported Results	Reactive, non-reactive, titer results	Same
Interpretation	Automated	Same
Sample processing	Automated	Same
Titer Diluent	PBS for low and moderate titer. GSD RPR Diluent for high and extra high titer.	PBS

6(b1): Nonclinical Studies:

Cross Reactivity

The study was conducted to evaluate potential cross reactivity from different disease conditions. A panel of antibodies from 17 different conditions (10 viral, 3 bacterial, and 4 autoimmune conditions) was obtained from serum brokers who confirmed the presence of each respective disease marker. The samples were tested on the GSD AIX1000 RPR Automated Test System. Each condition tested 10-16 individual patient samples. Reactive and non-reactive controls were run on each day of testing. The results are summarized below:

Positive For	Number Tested	Number Reactive
Rubella	10	0
Vericella Zoster Virus (VZV)	10	0
Human Immunodeficiency Virus (HIV)	10	0
Hepatitis B	16	0
Hepatitis C	11	0
Epstein Barr Virus (EBV)	10	0
Herpes Simplex Virus (HSV) Type 1	10	0
Herpes Simplex Virus (HSV) Type 2	10	0
Cytomegalovirus (CMV)	11	0
Heterophile antibodies*	10	0
Toxoplasma gondii	10	0
Leptospira biflexa	10	0
Borrelia burgdorferi	10	0

Systemic Lupus Erythematosus (SLE)	10	0
Rheumatoid Arthritis	10	0
Scleroderma	10	0
Primary Anti-phospholipid Syndrome	16	0

*Heterophiles samples were tested for infectious mononucleosis (EBV and un-related non-EBV heterophile antibodies).

Interfering Substances

The effect of potential interfering substances on samples using the GSD AIX1000 RPR Automated Test System was evaluated. The panel consisted of seven endogenous substances and two prescription drugs that could be used to treat syphilis patients. Five samples, one non-reactive and four reactive samples (with a concentration of 1:2, 1:4, 1:16, and 1:64 from four individual patients), were obtained from a serum broker and were tested in the presence (interferents spiked in-house at the concentration described below) or absence of interferents. The qualitative (non-titer) result was recorded for each sample. The concentrations selected were recommended in the Clinical and Laboratory Standards Institute standard document CLSI EP7-A2. Reactive and non-reactive controls were run on each day of testing. For all substances, the RPR samples remained positive, therefore the tested substances did not affect the performance of the GSD AIX1000 RPR Automated Test System.

Substance	Concentration	Interference
Hemoglobin	20 g/dL	None Observed
Bilirubin (unconjugated)	15 mg/dL	None Observed
Cholesterol	250 mg/dL	None Observed
Albumin	5 g/dL	None Observed
Gamma Globulin	60 g/L	None Observed
Glucose	120 mg/dL	None Observed
Triglyceride	500 mg/dL	None Observed
Antibiotic (Cephalexin)	337 umol/L	None Observed
Antibiotic (Tetracycline)	34 umol/L	None Observed

Precision

To test the precision of the GSD AIX1000 RPR Automated Test System, a within-lab precision study was conducted. This study was conducted in-house with clinical samples at the following concentrations: a low RPR reactivity (<1:8), a moderately reactive (1:16), a reactive (1:64), highly reactive (1:128), and a non-reactive serum (the highly reactive sample was a pooled sample, while all the other samples were individual patient sera). Each concentration level was tested in replicates of nine. These nine replicates were spread across five panels that were tested every day for five consecutive days by one operator using one instrument. The sample panels were masked and randomized. Reactive and non-reactive controls were run on each day of testing. The results are summarized below.

	End Point Titer Results	

Sample Reactivity	Non-reactive	Neat	1:2	1:4	1:8	1:16	1:32	1:64	1:128	≥1:256	% Agreement within ± 1 titer (95% C.I.)
Non-Reactive Serum	**45**	0	0	0	0	0	0	0	0	0	100% (93.6% - 100%)
Low RPR Reactivity (1:4)	0	0	**2**	**38**	**5**	0	0	0	0	0	100% (93.6% - 100%)
Moderately Reactive (1:16)	0	0	0	0	**27**	**18**	0	0	0	0	100% (93.6% - 100%)
Reactive (1:64)	0	0	0	0	0	**1**	**25**	**15**	**4**	0	97.8% (88.2% - 99.9%)
Highly Reactive (1:128)	0	0	0	0	0	0	0	**19**	**19**	**7**	100% (93.6% - 100%)
Reactive control	0	**5**	0	0	0	0	0	0	0	0	100% (54.9% – 100%)
Non-reactive control	**5**	0	0	0	0	0	0	0	0	0	100% (54.9% – 100%)

Reproducibility

To investigate operator-to-operator and instrument-to-instrument variability, six operators, three instruments, and two runs were tested each day over five consecutive days as outlined in the following testing schedule:

Operator & Instrument ID	Day 1		Day 2		Day 3		Day 4		Day 5	
	Run 1	Run 2	Run 1	Run 2	Run 1	Run 2	Run 1	Run 2	Run 1	Run 2
Operator 1, Instrument 1	Panel I		Panel II		Panel III		Panel IV		Panel V	
Operator 2, Instrument 1		Panel II		Panel III		Panel IV		Panel V		Panel I
Operator 3, Instrument 2	Panel III		Panel IV		Panel V		Panel I		Panel II	
Operator 4, Instrument 2		Panel IV		Panel V		Panel I		Panel II		Panel III
Operator 5, Instrument 3	Panel V		Panel I		Panel II		Panel III		Panel IV	

Operator 6, Instrument 3		Panel I		Panel II		Panel III		Panel IV		Panel V

Each operator tested the five sample panels (described in the Precision section above). The sample panels were masked and randomized. Reactive and non-reactive controls were run on each day of testing. The results are summarized below:

	End Point Titer Results										
Sample Reactivity	**Non-reactive**	**Neat**	**1:2**	**1:4**	**1:8**	**1:16**	**1:32**	**1:64**	**1:128**	**≥1:256**	**% Agreement within ± 1 titer (95% C.I.)**
Non-Reactive Serum	**54**	0	0	0	0	0	0	0	0	0	100% (94.5% - 100%)
Low RPR Reactivity (1:4)	0	0	**0**	**23**	**31**	0	0	0	0	0	100% (94.5% - 100%)
Moderately Reactive (1:16)	0	0	0	0	**7**	**42**	**5**	0	0	0	100% (94.5% - 100%)
Reactive (1:64)	0	0	0	0	0	**0**	**42**	**12**	**0**	0	100% (94.5% - 100%)
Highly Reactive (1:128)	0	0	0	0	0	0	**1**	**28**	**20**	**5**	98.1% (90.1% - 99.9%)
Reactive control	0	**30**	0	0	0	0	0	0	0	0	100% (90.5% – 100%)
Non-reactive control	**30**	0	0	0	0	0	0	0	0	0	100% (90.5% – 100%)

The sample agreement (within ± 1 titer) for between-runs, between-days, between-operators, and between-instruments are summarized below:

Sample Reactivity	**Between-Runs**	**Between-Days**	**Between-Operators**	**Between-Instruments**
Non-Reactive Serum	100%	100%	100%	100%
Low RPR Reactivity (1:4)	100%	100%	100%	100%

Moderately Reactive (1:16)	100%	100%	100%	100%
Reactive (1:64)	100%	97.8%	100%	100%
Highly Reactive (1:128)	100%	100%	98.1%	100%

Endpoint Titer Validation with highly reactive samples.

Reagin antibody endpoint titers were determined by the GSD AIX1000 RPR Automated Test System high-titer function, with six highly reactive clinical samples All samples were individual patient sera. Each concentration level was tested in replicates of four, twice per day by different operators for ten days. Reactive and non-reactive controls were run on each day of testing. The results are summarized below.

			Endpoint Titer Results							
Sample Reactivity	**Non-reactive**	**Reactive**	**1:16**	**1:32**	**1:64**	**1:128**	**1:256**	**1:512**	**1:1024**	**≥1:2048**
Sample 1	0	**80**	0	**61**	**19**	0	0	0	0	0
Sample 2	0	**80**	0	0	**14**	**47**	**19**	0	0	0
Sample 3	0	**80**	**1**	**76**	**3**	0	0	0	0	0
Sample 4	0	**80**	0	0	0	**54**	**21**	**5**	0	0
Sample 5	0	**80**						**54**	**23**	**3**
Sample 6	0	**80**						**34**	**32**	**14**
Reactive control	0	**60**								
Non-reactive control	20	**0**								

Comparison Study using Highly Reactive Samples

Five serum samples were tested on the GSD AIX1000 RPR Automated Test System and on the FDA cleared RPR assay in triplicates. The results are summarized below:

Sample ID	Comparator Result	AIX1000 Result
Sample 1	1:256 1:512 1:512	1:512 1:512 1:1024
Sample 2	1:256 1:256 1:512	1:512 1:512 1:512
Sample 3	1:512 1:512 1:512	1:512 1:512 1:512
Sample 4	1:512 1:1024 1:512	1:512 1:512 1:512
Sample 5	1:256 1:512 1:512	1:512 1:512 1:1024

Carry-over

The purpose of the carry-over study was to uncover the presence of contamination in negative specimens due to carry-over of RPR antibodies during sample processing on the GSD AIX1000 RPR Automated Test System. The study was conducted over three consecutive days on a single AIX1000 instrument. One reactive (1:64), one highly reactive (1:128) and two negative samples were tested over five runs. The samples used were from individual patients (not pooled). The qualitative (non-titer) result was recorded for each sample. Highly reactive samples were alternated with non-reactive samples (reactive 1 with non-reactive 1; reactive 1 with non-reactive 2- tested twice; reactive 2 with

non-reactive 1; and reactive 2 with non-reactive 2) 96 times per run. All 480 replicates of the negative samples were reported as non-reactive, therefore, no evidence of carry-over was observed.

6(b2): Clinical Studies:

i. Prospectively Collected Samples

Prospective sample collection was conducted at two geographically distinct (Southeastern and Western United States) reference laboratories that received samples from local clinics, hospitals, and doctor's offices. Testing was conducted at three sites (one in house and two locations that represented the intended use sited for the GSD AIX1000 RPR Automated Test System. For all testing sites, reactive and non-reactive external controls were tested with the assay on each day of testing. All 765 serum samples were collected prospectively from patient samples with a physician's order to perform syphilis testing. Samples were stored frozen (-20°C) for a maximum of five months before testing. All samples that were shipped, were transported and stored frozen until testing. All three sites performed their own comparator testing.

All prospectively collected samples were "de-identified", therefore, only pregnancy and HIV status was recorded. No information regarding gender, age, syphilis stage, or antibiotic use was available.

Seven hundred sixty five (765) serum samples were tested on both the GSD RPR Automated Test System and on the comparator device (cleared FDA Assay). The initial tests resulted in 26 invalid results (invalid rate of 3.4% with 95% CI: 2.33% - 4.93%). All 26 samples were re-tested and gave non-reactive results. The comparison of results for the prospectively collected clinical samples is summarized below:

Prospective Samples		**Comparator Device**		
		Reactive	Non-reactive	**Total**
GSD AIX1000 RPR Test System	Reactive	21	1*	22
	Non-reactive	1*	742	743
	Total	22	743	765

*The two discrepant samples were tested on a third FDA cleared RPR assay. Both samples were non-reactive on the third RPR assay.

The positive percent agreement and negative percent agreement of the GSD AIX1000 RPR Automated Test System with the comparator device (along with their 95% confidence intervals) are 95.5% (C.I. 77.2% - 99.9%) and 99.9% (C.I. 99.3% - 100%), %), respectively.

To further investigate the serologic status of the non-treponemal antibody positive samples (NT+), the samples that gave a reactive result either by the GSD AIX1000 RPR Automated Test System or by the comparator device were further tested on an FDA cleared treponemal (TP) assay. Of the 21 samples that were non-treponemal antibody reactive on both the GSD AIX1000 RPR Automated Test System and on the comparator device, only 18 (18/21 = 85.7%) had enough volume for further testing; all 18 samples were positive for TP antibodies. The one sample that was NT+ on the GSD AIX1000

Automated Test System and non-treponemal non-reactive (NT-) on the comparator device was negative for TP antibodies. The one sample that was NT- on the GSD AIX1000 Automated Test System and NT+ on the comparator device was negative for TP antibodies. The 742 samples that were concordant non-reactive with the test device and the comparator device did not receive further TP testing (742/765 = 97.0%).

ii. Retrospectively Collected Samples

In addition, 2,246 retrospectively collected samples from patients referred for syphilis testing were tested on the GSD AIX1000 RPR Automated Test System and on the comparator device. The samples were obtained from sample brokers who collect from multiple sites across the United States. The samples were collected between January 2005 and July 2014 and stored at -20°C until the time of testing. Samples included 607 men and 666 women ranging in age from 10 to 98 years (mean = 35 years. The gender and age of the remaining samples were not disclosed). All samples were tested in-house by a single operator. Reactive and non-reactive controls were tested with the assay on each day of testing. The initial tests resulted with six invalid results (invalid rate of 0.27% with 95% CI: 0.12% - 0.58%). All six samples were re-tested and gave one reactive and five non-reactive results. The results are summarized below:

Retrospective Samples		**Comparator Device**		
		Reactive	Non-reactive	**Total**
GSD AIX1000 RPR Test System	Reactive	556	15*	571
	Non-reactive	16*	1659	1675
	Total	572	1674	2246

*The 31 discrepant samples were tested on a third FDA cleared RPR assay. Of the 16 GSD non-reactive and comparator device reactive samples, the third RPR assay called 12 reactive and 4 non-reactive. Of the 15 GSD AIX1000 RPR Automated Test System reactive and comparator device non-reactive samples, the third RPR assay called 11 reactive and 4 non-reactive.

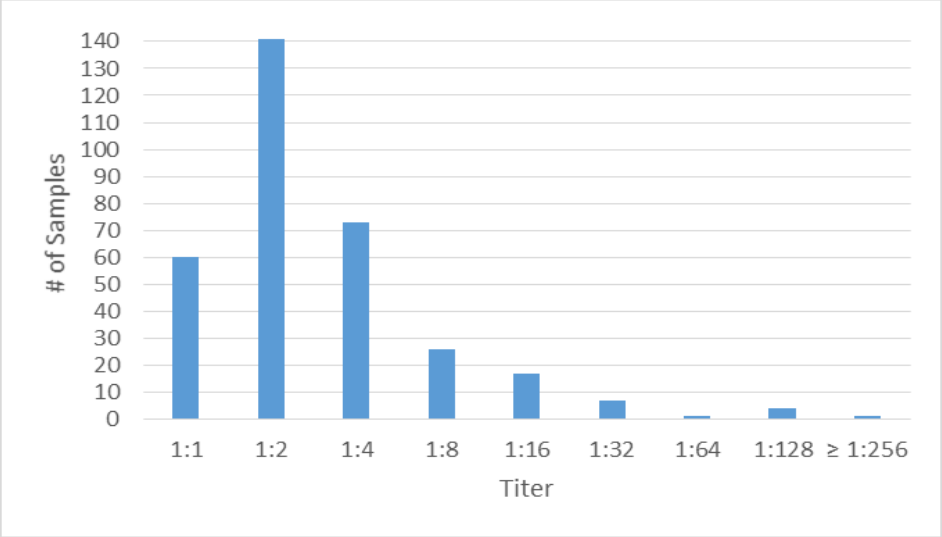
The positive percent agreement and negative percent agreement of the GSD AIX1000 RPR Automated Test System with the comparator device (along with their 95% confidence intervals) are 97.2% (C.I. 95.5% - 98.4%) and 99.1% (C.I. 98.5% - 99.5%), respectively.

To further investigate the serologic status of the non-treponemal antibody positive samples (NT+), the samples that gave a reactive result either by the GSD AIX1000 RPR Automated Test System or the comparator device were further tested on an FDA cleared treponemal (TP) assay. Of the 556 samples that were non-treponemal antibody reactive on both the GSD AIX1000 RPR Automated Test System and on the comparator device, only 404 had enough volume for further TP (404/556 = 72.7%). Of the 15 samples that were NT+ on the GSD AIX1000 RPR Automated Test System and non-reactive for non-treponemal antibodies (NT-) on the comparator device, only three had enough volume for further TP testing (9/16 = 56.3%). Of the 16 samples that were NT- on the GSD AIX1000 RPR Automated Test System and NT+ on the comparator device, only nine had enough volume for further TP testing. A total of 416 samples that were reactive by either the test device or the comparator device received further TP testing. Samples that were concordant non-reactive with the test device and the comparator device did not receive further TP testing. The results are summarized below:

		Comparator Device NT + / Trep +	Comparator Device NT + / Trep -	Comparator Device NT - / Trep +	Comparator Device NT - / Trep -
GSD AIX1000 NT Assay Result	Reactive	366	38	1	2
	Non-reactive	5	4	N/A*	N/A*

*Samples with concordant non-reactive results by the comparator device and the GSD AIX1000 RPR Automated Test System did not receive further TP testing.

Three hundred thirty (330) of the retrospective collected samples were tested for titer (330/587 samples collected = 56.2%). The frequency distribution of titer results from samples that are RPR reactive on the GSD AIX1000 RPR Automated Test System is shown in the figure below:



Distribution of Titer Results from Samples Designated as RPR Reactive on the GSD AIX1000 RPR Automated Test System.

iii. Retrospectively Collected Samples from Special Populations

Pregnant Women

In addition, 250 samples that were non-reactive for non-treponemal antibodies (NT-) were retrospectively collected from pregnant women at one site (Southeastern United States). The age of these women ranged from 15-44 years old (median = 29 years old) The samples were collected between July 2012 and August 2013 and stored at -20°C until the time of testing. To create non-treponemal antibody reactive (NT+) samples, sera from 30 individual pregnant women were collected and spiked with a pool created by combining highly reactive RPR positive samples.

Sera from 30 pregnant women were obtained and were tested on an FDA cleared Human Chorionic Gonadotropin (HCG) test to confirm the pregnancy status. All sera gave a positive HCG result. The 30 sera were then spiked with a pool of highly reactive (1:128 and 1:64) RPR positive samples. No more than 10% of the volume from the sera of pregnant women was supplanted by spiking. The spiked sera were tested again on the HCG test to confirm a positive result.

These samples were tested on the GSD AIX1000 RPR Automated Test System and on the comparator device. All samples were tested in-house by a single operator. The identity of the samples was masked. Reactive and non-reactive controls were tested with the assay on each day of testing. No invalid results were obtained. The results are summarized below:

Pregnant Women		**Comparator Device**		
		Reactive	Non-reactive	**Total**
GSD AIX1000 RPR Test System	Reactive	30	0	30
	Non-reactive	0	250	250
	Total	30	250	280

The positive percent agreement and negative percent agreement of the GSD AIX1000 RPR Automated Test System with the comparator (along with their 95% confidence intervals) are 100% (C.I. 90.5% - 100%) and 100% (C.I. 98.8% - 100%), %), respectively.

HIV Positive Individuals

In addition, 250 samples that were non-reactive for non-treponemal antibodies (NT-) and 30 samples that were reactive for non-treponemal antibodies (NT+) were retrospectively collected from HIV positive individuals at four sites (one Southeastern, one Mid-Western, and two Western States). The age ranged from 19-60 years old (median = 41 years). Sixteen (16) women and 71 men were included in this group (the age and gender of the other samples were not disclosed). The samples were collected between February 2012 and June 2015 and stored at -20°C until the time of testing.

These samples were tested on the GSD AIX1000 RPR Automated Test System and the comparator device. All samples were tested in-house by a single operator. The identity of the samples was masked and the samples from HIV positive individuals were randomized with samples collected from HIV negative individuals. Reactive and non-reactive controls were tested with the assay on each day of testing. No invalid results were obtained. The results are summarized below:

HIV Positive		**Comparator Device**		
		Reactive	Non-reactive	**Total**
GSD AIX1000 RPR Test System	Reactive	30	0	30
	Non-reactive	0	250	250
	Total	30	250	280

The positive percent agreement and negative percent agreement of the GSD AIX1000 RPR Automated Test System with the comparator (along with their 95% confidence intervals) are 100% (C.I. 90.5% - 100%) and 100% (C.I. 98.8% - 100%), respectively.

Apparently Healthy Individuals

To determine the percentage of RPR reactivity with the GSD AIX1000 RPR Automated Test System in a population of apparently healthy individuals, 100 serum samples prospectively collected from healthy individuals not at risk for syphilis and for whom a syphilis test had not been ordered (samples were submitted to the source laboratories for routine chemistry testing) were tested with the GSD

AIX1000 RPR Automated Test System. All 100 samples were non-reactive with the GSD AIX1000 RPR Automated Test System.

The percentage of RPR reactivity with the GSD AIX1000 RPR Automated Test system in the 765 prospective serum samples collected from two geographically distinct regions of the United States from patients with a physician's order to perform syphilis testing, 2.9% (22/765) were reactive with the GSD AIX1000 RPR Automated Test System.

Correlation with Clinically Diagnosed Syphilis Sera – Various Stages

A sample panel of sera collected from patients clinically positive for syphilis at various stages of the disease were purchased. The sera consisted of treated and untreated samples at the primary, secondary, and latent stages of syphilis. The age, gender, and collection dates for the samples were not disclosed. The primary syphilis samples given were characterized by documented genital lesion with positive dark field microscopy (if performed) and with reactive treponemal test. The secondary syphilis samples were characterized by documented rash or mucous patches or condyloma lata with reactive treponemal test. And the latent syphilis samples were characterized by having reactive treponemal and non-treponemal test with a non-reactive non-treponemal test for more than a year or for an unknown duration of infection.

The sera were tested on both the GSD AIX1000 RPR Automated Test System and on the comparator device. The sample panel members were masked and the order of testing was randomized. There were no invalid results reported in any of the tests. The results are summarized below:

	GSD AIX1000 RPR Test System and Comparator Device Results			
Clinical Diagnosis	**# Reactive***	**# Non-reactive***	**% Agreement**	**95% C.I.**
Primary Treated	13	0	100%	79.4% - 100%
Primary Untreated	12	0	100%	77.9% - 100%
Secondary Treated	25	0	100%	88.7% - 100%
Secondary Untreated	25	0	100%	88.7% - 100%
Latent Treated	25	0	100%	88.7% - 100%
Latent Untreated	25	0	100%	88.7% - 100%

*Note: The results of the sample population tested may not be consisted with what has been reported in the literature. It is important to perform follow-up testing on patients suspected of having syphilis.

7 Conclusion:

From the data, we conclude that the Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System is substantially equivalent to the predicate device K150358.