



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT**

I Background Information:

A 510(k) Number

K250249

B Applicant

Gold Standard Diagnostics, LLC.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GMQ	Class II	21 CFR 866.3820 - Treponema Pallidum Nontreponemal Test Reagents	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to add a new version of AIX1000 Analyzer with high titer function to the Gold Standard Diagnostics AIX1000 Rapid Plasma Reagin (RPR) Automated Test System (which consists of the Gold Standard Diagnostics RPR reagents and the AIX1000 Analyzer) and use of RPR diluent to prepare dilutions of highly reactive samples. This submission also includes several hardware and software changes made to the AIX1000 analyzer.

B Measurand:

Serum antibodies (cardiolipin and lecithin) against rapid plasma reagin

C Type of Test:

Non-treponemal macroscopic flocculation test

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

The GSD AIX1000 RPR Automated Test System uses the AIX1000 Analyzer. The AIX instrument automates sample preparation and results interpretation.

IV Device/System Characteristics:

A Device Description:

The GSD AIX1000 RPR Automated Test System is a non-treponemal test designed for the qualitative determination of reagin antibodies in human serum to aid in the diagnosis of syphilis. The test is also used to detect non-treponemal antibodies in samples that are serially diluted to establish titer information. The system consists of the AIX1000 Analyzer and RPR test reagents, where the AIX1000 Analyzer delivers serum from collection tubes into test wells, adds the antigen suspension, and then incubates the test wells while shaking them. An onboard camera creates a high-resolution image that is analyzed by proprietary software algorithms to interpret the results.

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, antibodies, if present, will bind to the antigen and form black flocculants due to the presence of carbon particles, while in

the absence of antibodies, the carbon particles remain evenly distributed. The antigen used in the GSD AIX1000 RPR Automated Test System is a modified VDRL carbon antigen with the same formulation established by the Centers for Disease Control and Prevention (CDC), containing 0.03% cardiolipin, 0.9% cholesterol, and 0.21% lecithin. The kit also includes untreated sterile 48-well reaction plates, a reactive control, a non-reactive control, and RPR diluent.

B Principle of Operation:

The GSD AIX1000 RPR Automated Test System is a flocculation test kit intended to be used with the AIX1000 Automated Analyzer. The instrument is intended to duplicate manual analytical procedures of a flocculation test by automating all necessary procedural steps. This is a non-treponemal macroscopic flocculation test that uses image capture and analysis to detect the presence of reagin. When reagin antibodies are present in a sample, they bind to their lipid antigens. Charcoal particles added to the solution co-agglutinate with these complexes and form black clumps that are macroscopically visible.

C Instrument Description Information:

1. Instrument Name:

AIX1000 Analyzer

2. Specimen Identification:

Specimens are identified by scanning a barcode or by manual entry.

3. Specimen Sampling and Handling:

Sample processing is automated by the AIX1000 Analyzer. The AIX1000 Analyzer is a fully automated microtiter plate processor that is able to completely perform sample processing steps, including dilutions, dispenses, and incubations.

4. Calibration:

Daily, weekly and monthly calibration and maintenance is required by the end user. These actions include instrument priming, instrument alignment, camera alignment, wash pump calibration, light intensity and camera integration time.

5. Quality Control:

The kit contains an external control set, consisting of a non-reactive control (human serum) and a reactive control (human serum reactive for syphilis)

V Substantial Equivalence Information:

A Predicate Device Name(s):

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

B Predicate 510(k) Number(s):

K150358

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K250249</u>	<u>K150358</u>
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 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.	The Gold Standard Diagnostics 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. 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

VI Standards/Guidance Documents Referenced:

- IEC 61010-1 Ed. 3.1 b:2017 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- ISO 14971:2019+A11:2021 Medical devices. Application of risk management to medical devices.
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Analytical studies supporting the GSD AIX1000 RPR Automated Test System in human serum were previously submitted and reviewed under K150358. In addition to the previously conducted studies, validating testing to incorporate dilution and detection of highly reactive samples in their titer function and use of RPR diluent was performed. A summary of study results is provided below.

1. Endpoint Titer Validation with Highly Reactive Samples

Four serum samples were tested using the AIX1000 Analyzer to evaluate endpoint titer validation and ensure that it is not affected by the GSD RPR diluent. The samples were tested in quadruplicate, twice a day, for 10 days with randomized three operators for a total N of 80 per sample. Additionally, two highly reactive serum samples were tested on the AIX1000 with the extra high titer function. The samples were tested in duplicate, twice per day by different operators for 20 days for a total N of 80 per sample. The results from the study are summarized o in Table 1.

Table 1. Results from Endpoint Titer Validation Study:

			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								

The data, as presented in Table 1, demonstrates that all replicates for each highly reactive sample were within ± 1 dilution for the GSD AIX1000 RPR Automated Test System using GSD RPR diluent.

2. Linearity:

N/A

3. Analytical Specificity/Interference:

Please refer to the decision summary of K150358.

4. Assay Reportable Range:

N/A

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Please refer to the decision summary of K150358.

6. Detection Limit:

N/A

7. Assay Cut-Off:

Please refer to the decision summary of K150358.

8. Carry-Over:

Please refer to the decision summary of K150358.

B Comparison Studies:

Comparison Study I:

Fifty samples were tested in parallel using both the previously FDA-cleared GSD AIX1000 RPR Automated Test System (with diluent according to the FDA-cleared Instructions for Use) and the modified version (with RPR diluent) to demonstrate equivalent performance between the two diluents. Samples were tested singly on all devices using retrospectively collected samples from laboratories and the titers were compared. The results are summarized in Table 2.

Table 2: Comparison Results

Sample ID	Cleared Version	Modified version
Sample 1	1:32	1:32
Sample 2 [#]	>= 1:256	>= 1:256
Sample 3	1:16	1:32
Sample 4	1:64	1:64
Sample 5	1:32	1:32
Sample 6	1:32	1:64
Sample 7	1:32	1:32
Sample 8	1:128	1:64
Sample 9	1:64	1:64
Sample 10	1:128	1:128

Sample 11	1:16	1:32
Sample 12	1:32	1:32
Sample 13	1:128	1:128
Sample 14	1:32	1:64
Sample 15	1:32	1:64
Sample 16	1:128	1:128
Sample 17	1:32	1:32
Sample 18	1:64	1:64
Sample 19	1:64	1:64
Sample 20	1:32	1:64
Sample 21 [#]	>= 1:256	>= 1:256
Sample 22	1:32	1:32
Sample 23	1:32	1:32
Sample 24	1:128	>= 1:256
Sample 25	1:32	1:64
Sample 26 [#]	>= 1:256	1:128
Sample 27 [#]	1:128	>= 1:256
Sample 28	1:128	1:64
Sample 29	1:32	1:32
Sample 30	1:64	1:64
Sample 31	1:64	1:64
Sample 32	1:64	1:64
Sample 33	1:32	1:32
Sample 34	1:16	1:32
Sample 35 [#]	>=1:256	>= 1:256
Sample 36	1:64	1:64
Sample 37	1:32	1:32
Sample 38	1:64	1:64
Sample 39	1:32	1:64
Sample 40	1:32	1:64
Sample 41	1:64	1:128
Sample 42	1:16	1:32
Sample 43	1:16	1:32
Sample 44	1:32	1:32
Sample 45	1:32	1:32
Sample 46	1:32	1:32
Sample 47	1:32	1:64
Sample 48	1:128	1:128
Sample 49	1:16	1:32
Sample 50	1:128	1:128

[#]The samples with results $\geq 1:256$ on the modified AIX1000 analyzer did not undergo higher titer testing, as the comparator lacked the extended high titer functionality that is only available on the new analyzer.

Titers obtained using the modified GSD AIX1000 RPR Automated Test System are within \pm one two-fold dilution of the titers determined by the previously cleared version.

Comparison Study II:

Five highly reactive serum samples were tested on the modified versions of the GSD AIX1000 RPR Automated Test System (using the RPR diluent) with the high titer and extra high titer function and on the FDA cleared RPR assay. The samples were tested in triplicate on both devices and the titers were compared. The results using highly reactive samples are summarized in Table 3.

Table 3: Comparison Using Highly Reactive Samples

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

All results from the GSD AIX1000 RPR Automated Test System are within ± 1 two-fold dilution of the results determined using the comparator assay.

C Clinical Studies:

Please refer to the decision summary of K150358.

D Clinical Cut-Off:

Please refer to the decision summary of K150358.

E Expected Values/Reference Range:

Please refer to the decision summary of K150358.

F Other Supportive Instrument Performance Characteristics Data:

N/A

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.