5.0 510(k) Summary

5.1 Preparation Date: 08/06/2020

Submitted By

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5.2 Trade Name – ASI Automated RPR test for Syphilis for use on the ASI Evolution

Regulation section: (21 CFR 866.3820) *Treponema pallidum* nontreponemal test reagents

Classification: Class II

Product Code: GMQ

Panel: Microbiology

5.3 Predicate Device(s) – ASI RPR Card Test for Syphilis on the ASI Evolution (K173376, BK170114, and K182391)

Device Similarities and Differences

Item	ASI Evolution (New Algorithm)	ASI Evolution (Original Algorithm)
Intended Use	The ASI Automated RPR (rapid plasma reagin) Test for Syphilis for use on the ASI Evolution, is a qualitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis. The ASI Evolution is intended to be used as a fully automated analyzer to objectively interpret the results of the ASI Automated RPR Test for Syphilis. The ASI Evolution is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results.	Same

	The ASI Automated RPR Test for Syphilis for use on the ASI Evolution is for professional use only. The test is intended to be used for blood donor screening. This test is not intended for diagnostic use.	
Technology Instruments	The ASI Evolution is an integrated digital particle analyzer designed to objectively interpret certain agglutination tests manufactured by Arlington Scientific, Inc. (ASI). The ASI Evolution fully automates the sample and reagent handling steps of the test procedure. Laboratory professionals use the ASI Evolution to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions. The ASI Evolution employs a camera to create a highly sensitive and high-resolution image of the agglutination immunoassay. This image is then analyzed by the proprietary software algorithm to interpret the agglutination pattern. The ASI Evolution further provides tools that enable the creation, storage, retrieval and transmittal of the test results.	Same
Technology Reagents	Flocculation Test	Same
Antigen	ASI RPR Carbon Antigen	Same
Reported Results	Reactive, Nonreactive	Same
Interpretation	Automated	Same
Sample Processing	Automated	Same
Reagent Volume used per Sample	110 µl	Same
Sample Type	Serum or Plasma	Same
Controls	Reactive, Weak Reactive, Nonreactive	Same
Test card	48 well plastic test plate	Same
Target Population	Used for *in vitro* diagnostic testing and blood donor testing.	Same

5.4 Device Description – The ASI Evolution is an integrated digital particle analyzer designed to objectively interpret certain slide agglutination tests manufactured by Arlington Scientific, Inc. (ASI). The ASI Evolution fully automates the sample and reagent handling steps of the test procedure. Qualitative tests are performed by laboratory professionals who use the ASI Evolution to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions.

The ASI Evolution employs a camera that uses light reflectance to create a highly sensitive and high-resolution image of the agglutination immunoassay. This image

is then analyzed by the proprietary software algorithm to interpret the agglutination pattern.

The ASI Evolution further provides tools that enable the creation, storage, retrieval and transmittal of the test results.

The ASI Automated RPR Test for Syphilis reagents include the following:

CARBON ANTIGEN - 0.003% cardiolipin, 0.020–0.022% lecithin, 0.09% cholesterol, charcoal (activated) as visual enhancer, phosphate buffer, 0.1% sodium azide as preservative and stabilizers.

CONTROLS (REACTIVE, WEAK REACTIVE, NONREACTIVE) - Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.

Reagents have two-year expiration dating from date of manufacture. The specific expiration date is located on the label on the vial.

Intended Use –

The ASI Automated RPR (rapid plasma reagin) Test for Syphilis for use on the ASI Evolution, is a qualitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis.

The ASI Evolution is intended to be used as a fully automated analyzer to objectively interpret the results of the ASI Automated RPR Test for Syphilis. The ASI Evolution is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results.

The ASI Automated RPR Test for Syphilis for use on the ASI Evolution is for professional use only. The test is intended to be used for blood donor screening. This test is not intended for diagnostic use.

Performance Data – The ASI Evolution was evaluated for equivalence in its pattern of reactivity against the ASiManager-AT. A total of 2,861 individual samples in 3,757 tests were conducted by the ASI Evolution compared with the ASiManager-AT, including a panel of 448 samples of known reactivity was tested at three sites: they yielded the same results and were counted only once in the statistical analysis. The distribution of the samples to the sites is represented in Table 1. The results were broken down for serum and plasma samples in Tables 2 and 3 respectively.

Table 1

Site	Prospective random samples		Retrospective samples[3]				A panel of known reactivity[3]		Total
			Plasma		Serum		Serum		
	Plasma[1]	Serum[2]	Known infected	Known Uninfected	Known infected	Known Uninfected	Known infected	Known Uninfected	
A	500	0	0	0	0	0	400	48	948
B	100	400	0	0	0	0	400	48	948
C	0	0	410	993	7	3	400	48	1,861
Total	**600**	**400**	**410**	**993**	**7**	**3**	**1,200**	**144**	**3,757**

[1] There were 3 concordant reactive results.
[2] There were 9 concordant reactive results and 4 discordant results (ASI Evolution nonreactive and ASiManager-AT reactive).
[3] All tests gave the expected results.

Combined prospective and retrospective (including one panel) results of testing serum samples on the ASI Evolution and the ASiManager-AT

Table 2

		ASI Evolution		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	416	4	420
	Nonreactive	0	438	438
	Total	416	442	858

The 4 discordant results (ASI Evolution nonreactive and ASiManager-AT reactive) were found to be nonreactive when tested with a treponemal test and a nontreponemal test. Below are the calculations for positive percentage agreement (PPA) and negative percentage agreement (NPA) including 95% confidence interval (CI) for serum samples.

PPA = 416/420 = 99.05% 95% CI: (97.58%, 99.74%)
NPA = 438/438 = 100% 95% CI: (99.16%, 100%)

ASI Evolution specificity for serum samples was calculated using prospective random samples excluding 9 confirmed positive samples (Table 1, footnote 2): 400 - 9 = 391. Sensitivity was calculated using known infected serum samples (Table 1): 400 + 7 = 407.

Specificity = 391/391 = 100% 95% CI: (99.06%, 100%)
Sensitivity = 407/407 = 100% 95% CI: (99.10%, 100%)

Combined prospective and retrospective results of testing plasma samples on the ASI Evolution and the ASiManager-AT

Table 3

		ASI Evolution		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	413	0	413
	Nonreactive	0	1590	1590
	Total	413	1590	2003

Below are the calculations for PPA and NPA including 95% CI for plasma samples.

PPA = 413/413 = 100% 95% CI: (99.11%, 100%)
NPA = 1590/1590 = 100% 95% CI: (99.77%, 100%)

ASI Evolution specificity for plasma samples was calculated using prospective random samples excluding 3 confirmed positive samples (Table 1, footnote 1): 600 - 3 = 597. Sensitivity was calculated using 410 known infected plasma samples (Table 1).

Specificity = 597/597 = 100% 95% CI: (99.38%, 100%)
Sensitivity = 410/410 = 100% 95% CI: (99.10%, 100%)

A total of 10 samples were evaluated to determine reproducibility of reactivity between three instruments. Of the 10 samples, 7 were reactive and 3 were nonreactive. The reactive samples had titers ranging from 1:1 to 1:256. Each of the 10 samples was analyzed once in each well of four different plates on each of the three instruments to evaluate the reactivity. The data are shown in Table 4.

Table 4

	Sample		**Results**						**% Agreement**
	Sample ID	Titer	Evolution 1		Evolution 2		Evolution 3		
1	R7C21R	1:8	R	192/192	R	192/192	R	192/192	100%
2	N7D04	NR	NR	192/192	NR	192/192	NR	192/192	100%
3	11114B	1:1	R	192/192	R	192/192	R	192/192	100%
4	11114C	1:1	R	192/192	R	192/192	R	192/192	100%
5	11114F	1:1	R	192/192	R	192/192	R	192/192	100%
6	02287	NR	NR	192/192	NR	192/192	NR	192/192	100%
7	08296	1:256	R	192/192	R	192/192	R	192/192	100%
8	11114D	1:1	R	192/192	R	192/192	R	192/192	100%
9	W7E26R	1:2	R	192/192	R	192/192	R	192/192	100%
10	N7H03	NR	NR	192/192	NR	192/192	NR	192/192	100%

The data above show that the ASI Evolution gives an objective and standardized interpretation of the test results with a high degree of reproducibility.

Cross Reactivity/Interfering Substances

A study was conducted to evaluate potential interference or cross reactivity from different disease conditions. Results are listed below:

Cross Reactivity/Interfering Substances

Specimen Category	Number of Samples	Expected Result	Result
ANA (+) Syphilis (-)	3	NR	NR
ASO (+) Syphilis (-)	2	NR	NR
CRP (+) Syphilis (-)	2	NR	NR
Infectious Mononucleosis* (+) Syphilis (-)	3	NR	NR
RF (+) Syphilis (-)	12	NR	NR
Rubella (+) Syphilis (-)	12	NR	NR
Lyme's (+) Syphilis (-)	12	NR	NR
HIV (+) Syphilis (-)	50	NR	NR
HIV (+) Syphilis (+)	24	R	R
Pregnancy (+) Syphilis (-)	250	NR	NR
Pregnancy (+) Syphilis (+)	30	R	R
Bilirubin 20 mg/dl	2	NR	NR
Hemoglobin 10 mg/ml	2	NR	NR
Triglycerides 1000mg/dl	2	NR	NR

*The positive infectious mononucleosis samples were heterophil antibody positive for the determination of disease state. EBV testing was not conducted.

The study showed no interference.

Carry-Over

A study was conducted to evaluate if contamination of a nonreactive sample due to carry-over from an adjacent reactive sample can occur.

- Testing was conducted at
  - Arlington Scientific, Inc.
- Testing was conducted using two different samples:
  - RPR reactive 1:64 tittered sample (high reactive) – Lot 06237
  - RPR nonreactive sample – Lot 06127
- The same samples were used for all testing.
- The same lot of carbon antigen was used – Lot CA7D24R
- Each test run was completed each day for five days by an operator with experience in performing the ASI RPR Card Test for Syphilis and operating the ASI Evolution.

- The test consisted of alternating 24 aliquots of the samples listed above in the sample rack and completing a run of 48 tests. Testing was performed on the same ASI Evolution.

The results of the testing are contained in table below:

Sample	Well Number	Expected	Results				
			ASiManager-AT #1				
		Date	08/11/17	08/14/17	08/15/17	08/16/17	08/17/17
06237	P1:A1	R	R	R	R	R	R
06127	P1:A2	NR	NR	NR	NR	NR	NR
06237	P1:A3	R	R	R	R	R	R
06127	P1:A4	NR	NR	NR	NR	NR	NR
06237	P1:A5	R	R	R	R	R	R
06127	P1:A6	NR	NR	NR	NR	NR	NR
06237	P1:A7	R	R	R	R	R	R
06127	P1:A8	NR	NR	NR	NR	NR	NR
06237	P1:B1	R	R	R	R	R	R
06127	P1:B2	NR	NR	NR	NR	NR	NR
06237	P1:B3	R	R	R	R	R	R
06127	P1:B4	NR	NR	NR	NR	NR	NR
06237	P1:B5	R	R	R	R	R	R
06127	P1:B6	NR	NR	NR	NR	NR	NR
06237	P1:B7	R	R	R	R	R	R
06127	P1:B8	NR	NR	NR	NR	NR	NR
06237	P1:C1	R	R	R	R	R	R
06127	P1:C2	NR	NR	NR	NR	NR	NR
06237	P1:C3	R	R	R	R	R	R
06127	P1:C4	NR	NR	NR	NR	NR	NR
06237	P1:C5	R	R	R	R	R	R
06127	P1:C6	NR	NR	NR	NR	NR	NR
06237	P1:C7	R	R	R	R	R	R
06127	P1:C8	NR	NR	NR	NR	NR	NR
06237	P1:D1	R	R	R	R	R	R
06127	P1:D2	NR	NR	NR	NR	NR	NR
06237	P1:D3	R	R	R	R	R	R
06127	P1:D4	NR	NR	NR	NR	NR	NR
06237	P1:D5	R	R	R	R	R	R
06127	P1:D6	NR	NR	NR	NR	NR	NR
06237	P1:D7	R	R	R	R	R	R
06127	P1:D8	NR	NR	NR	NR	NR	NR
06237	P1:E1	R	R	R	R	R	R
06127	P1:E2	NR	NR	NR	NR	NR	NR
06237	P1:E3	R	R	R	R	R	R
06127	P1:E4	NR	NR	NR	NR	NR	NR
06237	P1:E5	R	R	R	R	R	R
06127	P1:E6	NR	NR	NR	NR	NR	NR
06237	P1:E7	R	R	R	R	R	R
06127	P1:E8	NR	NR	NR	NR	NR	NR
06237	P1:F1	R	R	R	R	R	R
06127	P1:F2	NR	NR	NR	NR	NR	NR
06237	P1:F3	R	R	R	R	R	R
06127	P1:F4	NR	NR	NR	NR	NR	NR
06237	P1:F5	R	R	R	R	R	R
06127	P1:F6	NR	NR	NR	NR	NR	NR
06237	P1:F7	R	R	R	R	R	R
06127	P1:F8	NR	NR	NR	NR	NR	NR

These data demonstrate that all testing results were as expected and there was no evidence of contamination or carry-over.

A comparison of the digital interpretation of the results from the ASI Evolution using the original interpretation algorithm (K173376, BK170114, and K182391) to establish substantial equivalence to the interpretation made by the ASI Evolution using the new interpretation algorithm was conducted.

The ASI Evolution was evaluated for equivalence, in its pattern of reactivity using a total of 1,762 individual retrospective samples, with identifiers removed, that had been collected from different Departments of Public Health Labs and Blood Banks. Reactive, Weak Reactive and Nonreactive controls were run on each day of testing.

Retrospective Serum Sample Testing – 872 Samples

		ASI Evolution New Algorithm		
		Reactive	Nonreactive	Total
ASI Evolution Original Algorithm	Reactive	91	0	91
	Nonreactive	6	775	781
	Total	97	775	872

Note: The six discordant results were investigated and tested with a treponemal test and found to be reactive.

Serum positive agreement is calculated as:

91/(91 + 0) = 100%
95% CI = 96.03% - 100%

Serum negative agreement is calculated as:

775/(775 + 6) = 99.23%
95% CI = 98.34% - 99.72%

Serum samples were from both SST and Red Top tubes.

Retrospective Plasma Sample Testing – 890 Samples

		ASI Evolution New Algorithm		
		Reactive	Nonreactive	Total
ASI Evolution Original Algorithm	Reactive	119	5	124
	Nonreactive	1	765	766
	Total	120	770	890

Note: The six discordant results were investigated and the sample that was called reactive by the new algorithm and nonreactive by the original algorithm was tested with a treponemal test and found to be nonreactive. The five samples that were called nonreactive by the new algorithm and reactive by the original algorithm had bubbles or artifacts in the test well.

Total Plasma positive agreement is calculated as:

119/(119 + 5) = 95.97%
95% CI = 90.84% - 98.68%

Sodium Citrate positive agreement is calculated as:

55/(55 + 4) = 93.22%
95% CI = 83.54% - 98.12%

EDTA positive agreement is calculated as:

64/(64 + 1) = 98.46%
95% CI = 91.72% - 99.96%

Total Plasma negative agreement is calculated as:

765/(765 + 1) = 99.87%
95% CI = 99.27% - 100%

Sodium Citrate negative agreement is calculated as:

465/(465 + 1) = 99.79%
95% CI = 98.81% - 99.99%

EDTA negative agreement is calculated as:

300/(300 + 0) = 100%
95% CI = 98.78% - 100%

The positive and negative percent agreement for the two algorithms demonstrate that they have equivalent performance.

Reproducibility

Reproducibility testing was conducted. The testing consisted of:

- Testing seven (7) samples
  - 2 – RPR nonreactive samples
  - 2 – RPR reactive 1:2 titered samples
  - 1 – RPR reactive 1:4 titered sample
  - 1 – RPR reactive 1:8 titered sample
  - 1 – RPR reactive 1:16 titered sample
- Each sample was run in duplicate within the panel.
- Each sample was tested each day for five non-consecutive days by an operator with experience in performing the ASI Automated RPR Test for Syphilis
- Each sample was tested a second time on each of the days referenced above separated by approximately 2 hours.

Reproducibility Results

RPR (Rapid Plasma Reagin)				
Sample	***Sample #***	***N***	***Expected Result***	***95% Confidence Interval***
RPR nonreactive	10159A	60	100% (60/60)	94.04 - 100
RPR nonreactive	06127	60	100% (60/60)	94.04 - 100
RPR reactive 1:2	10159D	60	100% (60/60)	94.04 - 100
RPR reactive 1:2	W9P19R	60	100% (60/60)	94.04 - 100
RPR reactive 1:4	10159C	60	100% (60/60)	94.04 - 100
RPR reactive 1:8	10159E	60	100% (60/60)	94.04 - 100
RPR reactive 1:16	R0B03R	60	100% (60/60)	94.04 - 100

The data show a very high degree of reproducibility.

The conclusions drawn from the nonclinical and clinical studies demonstrate that the device is as safe, as effective, and performs as well as the predicate device.