June 14, 2018

Arlington Scientific, Inc. (ASI)
David Binks
COO/VP Regulatory
1840 North Technology Dr.
Springville, Utah 84663

Re: K173376
Trade/Device Name: ASI Automated RPR Test for Syphilis
ASI Evolution
Regulation Number: 21 CFR 866.3820
Regulation Name: Treponema pallidum nontreponemal test reagents
Regulatory Class: Class II
Product Code: GMQ
Dated: June 7, 2018
Received: June 8, 2018

Dear David Binks:

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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173376

Device Name

ASI Automated RPR Test for Syphilis
ASI Evolution

Indications for Use *(Describe)*

The ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Syphilis Analyzer, 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. All reactive RPR test samples should be further tested with a treponemal test. The ASI Automated RPR Test for Syphilis for use on the ASI Evolution produces only a reactive or non-reactive result and does not report RPR titers for reactive samples.

The ASI Automated RPR Test for Syphilis is for professional use only. The test is intended to be used for *in vitro* diagnostic testing.

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. It is intended to be acquired, possessed and used only by health care professionals. The ASI Evolution analyzer, in conjunction with the ASI Automated RPR Test is intended to be used for *in vitro* diagnostic testing. The ASI Automated RPR Test for Syphilis for use on the ASI Evolution produces only a reactive or non-reactive result and does not report RPR titers for reactive samples.

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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5.0 510(k) Summary

5.1 Preparation Date: 04/23/2018

Submitted By

David Binks MT (ASCP), MBA
COO/Vice President Regulatory
Arlington Scientific, Inc.
1840 North Technology Dr.
Springville, UT 84663
Phone 801-489-8911 / Fax 801-489-5552

5.2 Trade Name – ASI Automated RPR Test for Syphilis
ASI Evolution

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

Classification: Class II

Product Code: GMQ

Panel: Microbiology

5.3 Predicate Device(s) – ASI RPR Card Test for Syphilis on the ASiManager-AT (K851504)

Device Similarities and Differences

Item	**ASI Evolution**	**ASiManager-AT**
Intended Use	The ASI Automated RPR (rapid plasma reagin) Test for Syphilis, for use on the ASI Evolution Automated Syphilis Analyzer, 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. All reactive RPR test samples should be further tested with a treponemal test. The ASI Automated RPR Test for Syphilis for use on the ASI Evolution produces only a reactive or non-reactive result and does not report RPR titers for reactive samples. The ASI Automated RPR Test for Syphilis is for professional use only. The test is intended to be used for *in vitro* diagnostic testing. The ASI Evolution is intended to be used as a fully automated analyzer to objectively	The ASI RPR (rapid plasma reagin) Card Test for Syphilis is a qualitative and semiquantitative nontreponemal flocculation test for the detection of reagin antibodies in human serum and plasma as a screening test for serological evidence of syphilis. This test is also intended for use in screening blood donors and cadaveric (non-heart beating) donor specimens for tissue donation when the test is read and interpreted with the ASiManager-AT. The ASI RPR Card Test for Syphilis is for professional use only.

	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. It is intended to be acquired, possessed and used only by health care professionals. The ASI Evolution analyzer, in conjunction with the ASI Automated RPR Test is intended to be used for *in vitro* diagnostic testing. The ASI Automated RPR Test for Syphilis for use on the ASI Evolution produces only a reactive or non-reactive result and does not report RPR titers for reactive samples.	The ASiManager-AT is intended to be used as an integrated digital particle analyzer to objectively interpret the results of the ASI RPR Card Test for Syphilis. The ASiManager-AT is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results. It is intended to be acquired, possessed and used only by health care professionals. The ASiManager-AT is intended to be used for *in vitro* diagnostics, blood donor and cadaveric (non-heart beating) donor screening.
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 same proprietary interpretive algorithm used in the predicate device (ASiManager-AT) is used in the ASI Evolution. 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.	The ASiManager-AT is an integrated digital particle analyzer designed to objectively interpret certain slide agglutination tests manufactured by Arlington Scientific, Inc. (ASI). Qualitative and semiquantitative tests are performed by laboratory professionals who use the ASiManager-AT to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions. The ASiManager-AT 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 ASiManager-AT further provides tools that enable the creation, storage, retrieval and transmittal of the test results.
Technology Reagents	Flocculation Test	Same
Antigen	ASI RPR Carbon Antigen	Same
Reported Results	Reactive, Nonreactive	Same
Interpretation	Automated	Same
Sample Processing	Automated	Manual
Reagent Volume used per Sample	110 µl	105 µl
Sample Type	Serum or Plasma	Same
Controls	Reactive, Weak Reactive, Nonreactive	Same
Test card	48 well plastic test plate	30, 15, or 10 well plastic coated test card
Target Population	Used for *in vitro* diagnostic testing and blood donor testing.	Used for *in vitro* diagnostics testing, blood donor and cadaveric

		(non-heart beating) donor screening.

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 Evolutio**n 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. It is intended to be acquired, possessed and used only by health care professionals. The ASI Evolution analyzer, in conjunction with the ASI Automated RPR Test for Syphilis is intended to be used for in vitro diagnostic testing. The ASI Automated RPR Test for Syphilis for use on the ASI Evolution produces only a reactive or non-reactive result and does not report RPR titers for reactive samples.

The **ASI Automated RPR** (rapid plasma reagin) **Test for Syphilis,** for use on the ASI Evolution Automated Syphilis Analyzer, 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. All reactive RPR test samples should be further tested with a treponemal test. The ASI Automated RPR

Test for Syphilis for use on the ASI Evolution produces only a reactive or non-reactive result and does not report RPR titers for reactive samples.

The ASI Automated RPR Test for Syphilis is for professional use only. The test is intended to be used for in vitro diagnostic testing.

5.5 Clinical Data – A comparison of the digital interpretation of the results of testing samples with the ASI Automated RPR Test for Syphilis using the **ASI Evolution** and the ASiManager-AT by trained laboratory professionals was conducted to show substantial equivalence.

The ASI Evolution was evaluated for equivalence, in its pattern of reactivity, against the ASiManager-AT. A total of 1,068 individual prospective samples, with identifiers removed, were collected at two different Departments of Public Health Labs and tested by the ASI Evolution in comparison with the ASiManager-AT at each of the facilities. Reactive, Weak Reactive and Nonreactive controls were run on each day of testing.

The following data are the results from two testing sites:

Prospective Serum Sample Testing – 1,068 Samples

ASI Automated RPR Test for Syphilis on the ASI Evolution Result	ASI RPR Card Test for Syphilis on the ASiManager-AT Result	
	Reactive	Nonreactive
Reactive	114	1
Nonreactive	1	952

Using the data from the prospective performance results above, the positive agreement of the **ASI Evolution** can be calculated as:

114/(114 + 1) = 99.13**%**
95% CI = 95.25% - 99.98%

Using the data from the prospective performance results above, the negative agreement of the **ASI Evolution** can be calculated as:

952/(952 + 1) = 99.9**%**
95% CI = 99.42% - 100%

A total of 1,013 individual retrospective samples, with identifiers removed, were collected from various reference labs and serum and plasma vendors from across the United States and tested by the ASI Evolution in comparison with the ASiManager-AT

in-house. Reactive, Weak Reactive and Nonreactive controls were run on each day of testing.

Retrospective Serum Sample Testing – 10 Samples

		ASI RPR Card Test for Syphilis on the ASiManager-AT Result	
		Reactive	Nonreactive
ASI Automated RPR Test for Syphilis on the ASI Evolution Result	Reactive	7	0
	Nonreactive	0	3

Serum positive agreement is calculated as:

7/(7 + 0) = 100%
95% CI = 59.04% - 100%

Serum negative agreement is calculated as:

3/(3 + 0) = 100%
95% CI = 29.24% - 100%

Retrospective Plasma Sample Testing – 1,003 Samples

		ASI RPR Card Test for Syphilis on the ASiManager-AT Result	
		Reactive	Nonreactive
ASI Automated RPR Test for Syphilis on the ASI Evolution Result	Reactive	10	0
	Nonreactive	0	993

Sodium Citrate positive agreement is calculated as:

10/(10 + 0) = 100%
95% CI = 69.15% - 100%

Sodium Citrate negative agreement is calculated as:

993/(993 + 0) = 100%
95% CI = 99.63% - 100%

Distribution of Samples

Site	Prospective random samples			Retrospective samples			Grand Total
				Serum & Plasma			
	Plasma	Serum	Total	Known infected	Known Uninfected	Total	
a	0	567	567	0	0	0	567
b	0	501	501	0	0	0	501
c	0	0	0	17	996	1,013	1,013
total	0	1,068	**1,068**	17	996	**1,013**	**2,081**

ASI Evolution Characterized Specimen Testing

- Testing was conducted at:
  - Arlington Scientific, Inc. – Site C
- Carbon antigen lot used – Lot CA5K01RBA
- Each sample was tested by an operator with experience in performing the ASI Automated RPR Test for Syphilis and operating the ASI Evolution.
- ASI Evolution unit 5800-0102 (#1) used for testing
- Expected results are based on known clinical diagnosis
- All samples were serum

The results of the testing are contained in tables below:

Clinical Diagnosis	**No. Reactive**	**No. Nonreactive**	**% Agreement**	**95% CI**
Primary Treated	25	0	100%	86.28 – 100%
Primary Untreated	18	0	100%	81.47 – 100%
Secondary Treated	25	0	100%	86.28 – 100%
Secondary Untreated	25	0	100%	86.28 – 100%
Latent Treated	25	0	100%	86.28 – 100%
Latent Untreated	25	0	100%	86.28 – 100%

Performance with Samples from Pregnant Women:

Samples were collected from 250 pregnant women and tested on the ASI Evolution for reactivity. These samples were also tested using the ASiManager-AT. The age of these women ranged in age from 15 to 41 years old. (with a median age of 28 years old). All samples were nonreactive for syphilis when tested on the ASI Evolution. Samples were collected from 30 pregnant women that also had been diagnosed as having syphilis and were tested on the ASI Evolution for reactivity. The women ranged in age from 18 to 40 years old (with a median age of 28 years old). All samples were reactive for syphilis when tested on the ASI Evolution. All the samples were serum.

Pregnant Women Testing

ASI Automated RPR Test for Syphilis on the ASI Evolution Result		ASI RPR Card Test for Syphilis on the ASiManager-AT Result	
		Reactive	Nonreactive
	Reactive	30	0
	Nonreactive	0	250

Conclusion:

The positive and negative percent agreement for the ASI Evolution and the ASiManager-AT demonstrate that they have a very similar performance.

ASI Evolution Performance Characteristics

Precision

The interpretation of 10 samples using the ASI Automated RPR Test for Syphilis and the **ASI Evolution** were evaluated for reactivity. The testing requirements were as follows:

1. All qualitative testing was conducted according to the procedure listed in the package insert.
2. Each qualitative sample was tested 192 times. The number of replicates were chosen since the instrument can hold 4 – 48 well plates for a total of 192 wells. The 192 samples will test each well position.

A total of 10 samples were evaluated to determine repeatability of reactivity. Of the 10 samples:
3 were nonreactive
4- RPR reactive 1:1 titered samples
1- RPR reactive 1:2 titered sample
1- RPR reactive 1:8 titered sample
1- RPR reactive 1:256 titered sample

Each of the 10 samples was repeated 192 times to evaluate the reactivity using the **ASI Evolution**. An aliquot of the same sample was dispensed into 192 tubes. All 192 tubes were placed into the ASI Evolution and the run was performed. In this manner all 192 wells were tested with the same sample to show well to well and plate to plate repeatability using four test plates.

Precision Testing

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

The data above show that the **ASI Evolution** has a high degree of repeatability.

Reproducibility

Reproducibility testing was conducted at three sites. The testing consisted of:

- Testing seven (7) samples
  - 2 - RPR nonreactive samples
  - 1 – RPR reactive 1:2 titered samples
  - 1 – RPR reactive 1:4 titered sample
  - 2 - 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 and operating the ASI Evolution.
- Each sample was tested a second time on each of the days referenced above separated by approximately 2 hours.
- Testing at each site was performed on the same ASI Evolution.

RPR			Site 1		Site 2		Site 3		Total	
Sample	***Sample #***	***N***	***Expected Result***	***95% Confidence Interval***	***% Expected Result***	***95% Confidence Interval***	***% Expected Result***	***95% Confidence Interval***	***% Expected Result***	***95% Confidence Interval***
RPR nonreactive	02287	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100
RPR nonreactive	N6K14	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100
RPR reactive 1:2	05225B	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100
RPR reactive 1:4	07035	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100
RPR reactive 1:8	05225A	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100
RPR reactive 1:8	R7C21R	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100
RPR reactive 1:16	07117	180	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (60/60)	93.98 - 100	100% (180/180)	97.91 - 100

The data shows a very high degree of reproducibility.

Another reproducibility study was conducted at the three sites. All qualitative testing was conducted according to the procedure listed in the package insert. The testing consisted of:

- Testing 448 samples
  - 48 - RPR nonreactive samples
  - 400 – RPR reactive samples
- The same samples were tested at all three sites described above for the clinical and the previous reproducibility studies.
- All samples were retrospective serum.
- Samples, with identifiers removed, were collected from various reference labs and serum and plasma vendors from across the United States.
- Testing at each site was performed on the same ASI Evolution.
- Results were as follows:

RPR		Site 1		Site 2		Site 3		Total	
Sample	***N***	***Expected Result***	***95% Confidence Interval***	***% Expected Result***	***95% Confidence Interval***	***% Expected Result***	***95% Confidence Interval***	***% Expected Result***	***95% Confidence Interval***
RPR nonreactive	48	100% (48/48)	92.60 - 100	100% (48/48)	92.60 - 100	100% (48/48)	92.60 - 100	100% (144/144)	97.47 - 100
RPR reactive	400	100% (400/400)	99.08 - 100	100% (400/400)	99.08 - 100	100% (400/400)	99.08 - 100	100% (1200/1200)	99.69 - 100

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	# of samples with expected result/# of samples tests
ANA (+) Syphilis (-)	3	NR	3/3
ASO (+) Syphilis (-)	2	NR	2/2
CRP (+) Syphilis (-)	2	NR	2/2
Infectious Mono (+) Syphilis (-)	3	NR	3/3
RF (+) Syphilis (-)	12	NR	12/12
Rubella (+) Syphilis (-)	12	NR	12/12
Lyme's (+) Syphilis (-)	12	NR	12/12
HIV (+) Syphilis (-)	50	NR	50/50
HIV (+) Syphilis (+)	24	R	24/24
Pregnancy (+) Syphilis (-)	250	NR	250/250
Pregnancy (+) Syphilis (+)	30	R	30/30
Bilirubin 20 mg/dl	2	NR	2/2
Hemoglobin 10 mg/ml	2	NR	2/2
Triglycerides 1000mg/dl	2	NR	2/2

The positive infectious mono samples were heterophile positive. 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) – 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 Automated RPR 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.

Carry-Over Testing

ASI Automated RPR Test for Syphilis on the ASI Evolution Result		Expected Results	
		Reactive	Nonreactive
	Reactive	24	0
	Nonreactive	0	24

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

ASI Evolution On-board Stability Testing

- Testing was conducted at:
  - Arlington Scientific, Inc. – Site C
- Testing was conducted using four different samples:
  - RPR nonreactive sample – Lot 12313
  - RPR reactive 1:2 tittered sample (low reactive) – LR0646530
  - RPR reactive 1:16 tittered sample (moderate reactive) – LB0482464
  - RPR reactive 1:64 tittered sample (high reactive) – OL0500976
- The same samples were used for all testing.
- The same lot of carbon antigen was used – Lot CA5K01RBA
- Each sample was tested each morning for five days by an operator with experience in performing the ASI Automated RPR Test for Syphilis and operating the ASI Evolution.
- Each sample was tested each afternoon for five days by a different operator with experience in performing the ASI Automated RPR Test for Syphilis and operating the Evolution.
- The carbon antigen reagent was left on the ASI Evolution between runs for a total elapsed time of 8 hours.
- The carbon antigen was stored at 2-8° C between the afternoon test run and the next morning test run (overnight)
- Each of the four samples was run in triplicate on the morning and afternoon runs.
- ASI Evolution unit 5800-0102 (#1) used for testing
- All samples were serum.

The results of the testing are contained in table below:

On-board Stability Testing

Sample	Expected	Results					% Agreement
		ASI Evolution					
Operator 1		Day 1	Day 2	Day 3	Day 4	Day 5	
12313	NR	3/3	3/3	3/3	3/3	3/3	100%
LR0646530	R	3/3	3/3	3/3	3/3	3/3	100%
LB0482464	R	3/3	3/3	3/3	3/3	3/3	100%
OL0500976	R	3/3	3/3	3/3	3/3	3/3	100%
Operator 2							
12313	NR	3/3	3/3	3/3	3/3	3/3	100%
LR0646530	R	3/3	3/3	3/3	3/3	3/3	100%
LB0482464	R	3/3	3/3	3/3	3/3	3/3	100%
OL0500976	R	3/3	3/3	3/3	3/3	3/3	100%

Using this data the following evaluations can be made:

All testing results were as expected.

The carbon antigen reagent is stable on the instrument for up to 8 hours.

ASI Evolution Frozen vs Refrigerated Testing

- Testing was conducted at:
  - Arlington Scientific, Inc. – Site C
- Carbon antigen Lot used – Lot CA5K01RBA
- Each sample was tested by an operator with experience in performing the ASI Automated RPR Test for Syphilis and operating the ASI Evolution.
- ASI Evolution unit 5800-0102 (#1) used for testing.
- Each sample was split into two aliquots. One was stored at 2-8° C and the other one was frozen. The frozen specimens were allowed to remain frozen for 1 month and then were thawed.
- All testing was done on the ASI Evolution.
- All specimens were allowed to come to room temperature before testing.

Frozen vs. Refrigerated Testing

Sample Titer	N	Fresh Samples	Frozen Samples
		% Expected Result (# expected result/N)	% Expected Result (# expected result/N)
Not Reactive	20	100% (20/20)	100% (20/20)
1:1	20	100% (20/20)	100% (20/20)
1:2	5	100% (5/5)	100% (5/5)
1:4	5	100% (5/5)	100% (5/5)
1:8	3	100% (3/3)	100% (3/3)
1:16	2	100% (2/2)	100% (2/2)

All samples gave the expected results.