Arlington Scientific, Inc.

ASI RPR Test for Syphilis For Use on the ASI Evolution®

This test is intended for use in screening blood donors.

For in vitro diagnostic use	R_x Only
Catalog Number	**Kit Size**
900480A	480 Tests
9004800A	4800 Tests
CPT Code 86592 (Screening), CPT Code 85693 (Titers)	

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

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

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 Evolution analyzer, in conjunction with the ASI Automated RPR Test for Syphilis is intended to be used for in vitro diagnostic testing and blood donor screening.

SUMMARY AND EXPLANATION: Treponema pallidum, the etiological agent of syphilis, induces the production of at least two types of antibodies in human infection: anti-treponemal antibodies that can be detected by FTA-ABS antigen[1], and anti-nontreponemal antibodies (reagin) that can be detected by RPR antigen[2].

PRINCIPLE OF THE PROCEDURE: The **ASI Automated RPR Test for Syphilis** is an automated macroscopic nontreponemal flocculation test to be used for the detection of reagin. This test kit is intended to be used with the ASI Evolution Automated Syphilis Analyzer. The ASI Evolution instrument automates the dispensing of serum or plasma samples and the dispensing of carbon antigen reagent. The microparticulate carbon RPR antigen enhances the visual discrimination between reactive and nonreactive results. The reagin-type antibody binds with the antigen that is composed of a complex of cardiolipin, lecithin and cholesterol particles with activated charcoal. The result of this antigen-antibody reaction is macroscopic flocculation. The ASI Evolution uses an internal camera and image processing algorithm to read the RPR agglutination reaction and report a reactive or non-reactive result. The analyzer is also capable of performing end-point titers.

REAGENTS

- **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.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.

1. ASI AUTOMATED RPR REAGENTS contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide buildup.
2. ASI AUTOMATED RPR CONTROLS contain human serum or plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the CONTROLS should be considered potentially infectious and universal precautions should be used. The CDC/NIH Health Manual "Biosafety in Microbiological and Biomedical Laboratories" describes how these materials should be handled in accordance with Good Laboratory Practice.
3. Do not pipet by mouth.
4. Do not smoke, eat, drink or apply cosmetics in areas where plasma/serum samples are handled.
5. Any cuts, abrasions or other skin lesions should be suitably protected.

HANDLING AND PROCEDURAL NOTES

1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples.
2. Do not use past the expiration date indicated on the kit.
3. Do not interchange components from this kit with those of a different manufacturer.

STORAGE INSTRUCTIONS

Store all reagents at 2–8°C in an upright position when not in use. Do not freeze reagents.

INDICATIONS OF DETERIORATION

1. Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
2. Bacterial contamination of reagents or specimens may cause false positive results.

SPECIMEN COLLECTION AND STORAGE

1. Use either serum or Sodium Citrate plasma specimens for testing with the ASI Automated RPR Test for Syphilis on the ASI Evolution instrument; the use of other anticoagulants has not been evaluated.
2. Samples should be free from bacterial contamination, gross hemolysis, or lipemia. A specimen is too hemolyzed for testing when printed matter cannot be read through it[2].
3. Serum samples should be tested within five (5) days of collection. Samples should be stored at 2-8° C. Samples that require longer than five (5) days storage must be removed from the red cells and stored at -20° C or below until testing[2].
4. Plasma samples stored longer than five (5) days at 2-8° C should not be used in the assay because of the potential for false reactive results.
5. If necessary before testing, centrifuge the specimens at a force sufficient to sediment cellular components.
6. Samples to be sent out for testing should be placed on ice packs and packaged like any other biohazardous material that could potentially transmit infection.
7. This test should not be used for testing spinal fluids.

PERFORMANCE OF THE TEST

Materials Provided:

	480 Tests	4800 Tests
RPR CARBON ANTIGEN	22 ml	22 ml x 10
MICROWELL PLATES (48 well)	10	100

Control sets available

TEST PROCEDURE - Qualitative/Semiquantitative

1. Create or select a work list.
2. Load samples as work list is created.
3. Load carbon antigen reagent. Vigorously agitate the carbon antigen for 20-30 seconds before placing the vial into the reagent rack. Ensure that stir bar is in vial.
4. Select test to perform. R/NR for qualitative testing and Titer for Semiquantitative testing
5. Name work list.
6. Close Cover
7. Press start
8. Dispose of used microtiter plates in accordance with federal (40 CFR 261.3), state, local or Good Laboratory Practice requirements.

See Operator's Manual for complete instructions.

QUALITY CONTROL

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Support at 800-654-0146.

LIMITATIONS OF THE PROCEDURE

1. The device should not be used for syphilis testing with the Reverse Testing Algorithm (when treponemal testing is conducted first). This device should only be used when RPR testing is conducted before any follow up treponemal assays.
2. Prozone reactions can occur in patients with secondary syphilis[5]. False negative nontreponemal test results, arising from prozone, can also be seen in incubating primary and in late syphilis[2]. The nonreactive pattern is slightly granular or "rough" with specimens exhibiting prozone. When this pattern is exhibited, a dilution of the specimen should be prepared. Titer the diluted specimen until endpoint is reached or until no reactivity is observed. All tests exhibiting a rough appearance should be further evaluated.
3. Biological false positive reactions occur occasionally with the carbon antigen. Such reactions sometimes occur in samples from individuals with a history of drug abuse, pregnancy or with diseases such as lupus erythematosus, malaria, vaccinia, mononucleosis, leprosy, viral pneumonia, and after smallpox vaccinations.
4. Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test[2].
5. Contaminated, lipemic, icteric or grossly hemolyzed sera should not be used because of the possibility of nonspecific reactions. A specimen is too hemolyzed for testing when printed matter cannot be read through it[2].
6. The cover of the ASI Evolution should be closed while tests are being performed to avoid glare from outside lighting sources.
7. Reactive RPR test samples should be followed up with treponemal antibody testing as recommended in the Manual of Tests for Syphilis[2, 6].
8. Temperature of the reagents and samples is crucial to test outcome; it should be between 20-30°C.
9. A final diagnosis should not be made on the result of a single test but should be based on a correlation of test results with other clinical findings.

PERFORMANCE CHARACTERISTICS

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

Prospective Sample Testing – 1,068 Samples

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

Using the data from the prospective performance results above, the positive percent agreement of the ASI Automated RPR Test for Syphilis on the ASI Evolution was:

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

Using the data from the prospective performance results above, the negative percent agreement of the ASI Automated RPR Test for Syphilis on the ASI Evolution was:

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

A total of 1,013 individual retrospective samples (10 serum, 1003 plasma), with identifiers removed, were collected from various reference labs and serum and sodium citrate plasma vendors from across the United States and tested by the ASI Automated RPR Test for Syphilis on the ASI Evolution in comparison with the ASI RPR Card Test for Syphilis on the ASiManager-AT Results. 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 Results	
		Reactive	**Nonreactive**
ASi Automated RPR Test for Syphilis on the ASI Evolution Results	**Reactive**	7	0
	Nonreactive	0	3

Serum positive percent agreement was:

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

Serum negative percent agreement was:

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 Results	
		Reactive	**Nonreactive**
ASi Automated RPR Test for Syphilis on the ASI Evolution Results	**Reactive**	10	0
	Nonreactive	0	993

Sodium Citrate plasma positive percent agreement was:

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

Sodium Citrate plasma negative percent agreement was:

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

Distribution of Samples

Site	Prospective random samples			Restrospective samples			Grand Total
				Serum & Plasma			
	Plasma	Serum	Total	Known infected	Known Uninfected	Total	Known Uninfected
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
	0	1,068	**1,068**	17	996	**1,013**	**2,081**

ASI Automated RPR Test for Syphilis on the 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 Automated RPR Test for Syphilis on the ASI Evolution for reactivity. These samples were nonreactive for nontreponemal antibodies when tested using the ASI RPR Cart Test for Syphilis on 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 when tested with the ASI Automated RPR Test for Syphilis on the ASI Evolution and the comparator. Samples collected from 30 pregnant women that had been diagnosed as having syphilis and, were reactive by the comparator nontreponemal test, were tested with the ASI Automated RPR Test for Syphilis 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 with the ASI Automated RPR Test for Syphilis. All the samples were serum.

Pregnant Women Testing

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

Conclusion:
The positive and negative percent agreement between the ASI Automated RPR Test for Syphilis on the ASI Evolution and the ASI RPR Card Test for Syphilis on the ASiManager-AT demonstrate that they have a very similar performance.

ASI Automated RPR Test for Syphilis on the ASI Evolution Performance Characteristics

Precision:
The interpretation of 10 samples using the ASI Automated RPR Test for Syphilis on 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 four 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 of the ASI Automated RPR Test for Syphilis on 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			Results		% 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 demonstrate that the ASI Automated RPR Test for Syphilis on the ASI Evolution is adequately repeatable for a qualitative result.

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 sample
  - 1 – RPR reactive 1:4 titered sample
  - 2 – RPR reactive 1:8 titered samples
  - 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.
- 3 lots were tested each day.
- Testing at each site was performed on the same ASI Evolution instrument.

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 adequate reproducibility for qualitative results.

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 titered 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

		Expected Results	
		Reactive	**Nonreactive**
ASI Evolution Results	**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.

End-Point Titration Testing

A randomized and blinded panel of 10 human serum samples with known reagin antibody endpoint titers, as determined by the ASI RPR Card Test for Syphilis on the ASiManager-AT, were tested with the ASI Automated RPR Test for Syphilis on the ASI Evolution using the semiquantitative test procedure. The reactive samples had titers ranging from 1:1 to 1:256. Each sample panel member was tested a minimum of 80 times on at least five different days by a single operator using a single ASI Evolution instrument. All nonreactive samples must yield nonreactive test results, while all reactive samples must yield results that are within one dilution above or below the known titer. The results of the semiquantitative analysis are shown below.

Endpoint Titer Results												
Sample Reactivity	Nonre-active	Neat (1:1)	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	% Agreement within +/- 1 titer (95% C.I.)
06127 (Nonreactive)	80	0	0	0	0	0	0	0	0	0	0	100% (95.49% - 100%)
N8E23 (Nonreactive)	80	0	0	0	0	0	0	0	0	0	0	100% (95.49% - 100%)
W6A16R (1:2)	0	7	69	4	0	0	0	0	0	0	0	100% (95.49% - 100%)
W8B01R (1:2)	0	0	75	5	0	0	0	0	0	0	0	100% (95.49% - 100%)
R7F01R (1:8)	0	0	0	0	76	4	0	0	0	0	0	100% (95.49% - 100%)
R8B01R (1:8)	0	0	0	32	48	0	0	0	0	0	0	100% (95.49% - 100%)
07117 (1:16)	0	0	0	0	5	75	0	0	0	0	0	100% (95.49% - 100%)
08188 (1:64)	0	0	0	0	0	0	0	87	1	0	0	100% (95.89% - 100%)
07098 (1:128)	0	0	0	0	0	0	0	5	82	1	0	100% (95.89% - 100%)
08296 (1:256)	0	0	0	0	0	0	0	0	21	65	4	100% (95.98% - 100%)

All nonreactive samples were nonreactive, and all remaining samples were within one dilution of the known titer for an overall percent agreement of 100%.

Nine samples were tested in eight replicates on seventeen different days. Not all samples were tested on the same day. Each sample set of eight replicates were tested ten times giving a total of 80 data points for each sample. The line item data is included with this submission as a separate document. An acceptable result is within +/- 1 titer of the expected result. Nonreactive samples must be nonreactive. The results of the semiquantitative analysis samples are shown in the table below:

Titration Sample Testing

Sample ID	06127	N8E23	R7F01R	W6A16R	W8B01R	R8B01R	08188	07098	08296
Expected Result	NR	NR	1:8	1:2	1:2	1:8	1:64	1:128	1:256
Run									
1	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
2	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
3	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
4	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
5	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
6	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
7	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
9	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
10	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8	8/8
Total	80/80	80/80	80/80	80/80	80/80	80/80	80/80	80/80	80/80

All titration samples were within the +/- one titer.

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

560/(560 + 0) = 100%
95% CI = 99.34% - 100%

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

160/(160 + 0) = 100%
95% CI = 97.72% - 100%

REFERENCES

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TECHNICAL INFORMATION: (801) 489-8911 or (800) 654-0146

Arlington Scientific, Inc.
1840 North Technology Drive
Springville, UT 84663
info@arlingtonscientific.com
www.arlingtonscientific.com