5.0 510(k) Summary

5.1 Preparation Date: 10/09/2020

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

510(k) number – BK200539 – refer to 510(k) BK200488 for performance data associated with the blood donor claim.

5.3 Predicate Device(s) – ASI RPR Card Test for Syphilis on the ASI Evolution (K173376, BK170114, K182391 and BK200488)

Device Similarities and Differences

Item	ASI Evolution for testing cadaveric specimens for tissue donations.	ASI Evolution for testing blood donor specimens
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	Same, except cadaveric claim

	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 and for cadaveric (non-heart beating) donor specimens for tissue donation. 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 and cadaveric (non-heart beating) donor specimens for tissue donation. This test is not intended for diagnostic use.

Performance Data –

Cadaveric Donor Specimens:
A total of 164 serum samples, collected in SST (90) and red top tubes (74), with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution.

All the cadaveric specimens were collected within 24 hours of death. All specimens were shipped with ice packs by overnight delivery to ASI.

After initial testing, the nonreactive samples were spiked with a serum sample. The resulting spiked samples had titers ranging from 1:2 to 1:16.

Each sample was evaluated for the degree of hemolysis. The amount of hemolysis in the samples ranged from none to a heavy degree.

The results of the qualitative analysis of the serum samples collected in red top tubes (prior to and after spiking with reactive sample) are shown in Table 1:

Table 1. Serum Sample (Red Top) Testing - 74 Samples

Known Nonreactive

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	74	74
	Total	0	74	74

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	74	0	74
	Nonreactive	0	0	0
	Total	74	0	74

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

The results of the qualitative analysis of the serum samples collected in SST tubes (prior to and after spiking with reactive sample) are shown in Table 2:

Table 2. Serum Sample (SST) Testing - 90 Samples

Known Nonreactive

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	90	90
	Total	0	90	90

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	90	0	90
	Nonreactive	0	0	0
	Total	90	0	90

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

A total of 84 EDTA plasma samples, with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution.

After initial testing, the nonreactive samples were spiked with a serum sample. The resulting spiked samples had titers ranging from 1:2 to 1:16.

Each sample was evaluated for the degree of hemolysis. The amount of hemolysis in the samples ranged from none to a heavy degree.

The results of the qualitative analysis of the samples collected from EDTA plasma tubes (prior to and after spiking with reactive sample) are shown in Table 3:

Table 3. EDTA Plasma Sample Testing - 84 Samples

Known Nonreactive

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	84	84
	Total	0	84	84

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	84	0	84
	Nonreactive	0	0	0
	Total	84	0	84

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

Living Donor Specimens:

A total of 126 serum samples, collected in SST (51) and red top (75) tubes, with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution.

The results of the qualitative analysis of the serum samples collected in red top tubes (prior to and after spiking with reactive sample) are shown in Table 4:

Table 4. Serum Sample (Red Top) Testing - 75 Samples

Known Nonreactive

ASI Evolution Results

		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	75	75
	Total	0	75	75

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	75	0	75
	Nonreactive	0	0	0
	Total	75	0	75

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

The results of the qualitative analysis of the serum samples collected in SST tubes (prior to and after spiking with reactive sample) are shown in Table 5:

Table 5. Serum Sample (SST) Testing – 51 Samples

Known Nonreactive

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	51	51
	Total	0	51	51

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	51	0	51
	Nonreactive	0	0	0
	Total	51	0	51

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

A total of 76 EDTA plasma samples, with identifiers removed were tested to determine patterns of reactivity using the qualitative RPR test with the ASI Automated RPR Test procedure on the ASI Evolution. The results of the qualitative analysis of the samples collected from EDTA plasma tubes (prior to and after spiking with reactive sample) are shown in Table 6:

Table 6. EDTA Plasma Sample Testing - 76 Samples

Known Nonreactive

	ASI Evolution Results		
	Reactive	Nonreactive	Total

ASiManager-AT Results	Reactive	0	0	0
	Nonreactive	0	76	76
	Total	0	76	76

Spiked Samples

		ASI Evolution Results		
		Reactive	Nonreactive	Total
ASiManager-AT Results	Reactive	76	0	76
	Nonreactive	0	0	0
	Total	76	0	76

Review and analysis of the data for the samples give a percent agreement of 100% for nonreactive samples and 100% for reactive samples.

ASI Evolution Performance Characteristics

Positive Agreement

Using the data from the composite performance results above, the positive agreement of the **ASI Evolution** can be calculated using the following formula:

Positive Agreement = TR/TR+FN

where

TR = True Reactive, the number of samples that test reactive which actually are reactive.

FN = False Nonreactive, the number of samples that test nonreactive which actually are reactive.

Using this formula, the positive agreement is calculated as:

Cadaveric Donor Serum (Red Top)	Cadaveric Donor Serum (SST)	Cadaveric Donor Plasma (EDTA)
74/(74+0) = **100%**	90/(90+0) = **100%**	84/(84+0) = **100%**
95% CI = 95.14% - 100%	95% CI = 95.98% - 100%	95% CI = 95.70% - 100%

Living Donor Serum (Red Top)	Living Donor Serum (SST)	Living Donor Plasma (EDTA)
75/(75+0) = **100%**	51/(51+0) = **100%**	76/(76+0) = **100%**
95% CI = 95.20% - 100%	95% CI = 93.02% - 100%	95% CI = 95.26% - 100%

Negative Agreement

Using the data from the composite performance results above the negative agreement of the **ASI Evolution** can be calculated using the following formula:

Negative Agreement = TN/TN+FR

where

TN = True Nonreactive, the number of samples that test nonreactive which actually are nonreactive.

FR = False Reactive, the number of samples that test reactive which actually are nonreactive.

Using this formula, the negative agreement is calculated as:

Cadaveric Donor Serum (Red Top)	Cadaveric Donor Serum (SST)	Cadaveric Donor Plasma (EDTA)
74/(74+0) = **100%**	90/(90+0) = **100%**	84/(84+0) = **100%**
95% CI = 95.14% - 100%	95% CI = 95.98% - 100%	95% CI = 95.70% - 100%

Living Donor Serum (Red Top)	Living Donor Serum (SST)	Living Donor Plasma (EDTA)
75/(75+0) = **100%**	51/(51+0) = **100%**	76/(76+0) = **100%**
95% CI = 95.20% - 100%	95% CI = 93.02% - 100%	95% CI = 95.26% - 100%

Sensitivity and Specificity

The sensitivity of the **ASI Evolution** using cadaveric and living donor samples can be calculated using the data from the performance results of the spiked samples. The sensitivity was determined by spiking the nonreactive specimens with one of five RPR reactive samples.

The specificity of the **ASI Evolution** using cadaveric and living donor samples was calculated using the data from the performance results of the nonreactive samples.

Serum – SST

Clinical Specificity (random donors)		Analytical Sensitivity (spiked samples)	
Cadaveric	Living	Cadaveric	Living
90/90+0 = 100%	51/51+0 = 100%	90/90+0 = 100%	51/51+0 = 100%
95% CI = 95.98 – 100%	95% CI = 93.02 – 100%	95% CI = 95.98 – 100%	95% CI = 93.02 – 100%

Serum – Red Top

Clinical Specificity (random donors)		Analytical Sensitivity (spiked samples)	
Cadaveric	Living	Cadaveric	Living
74/74+0 = 100%	75/75+0 = 100%	74/74+0 = 100%	75/75+0 = 100%
95% CI = 95.14 – 100%	95% CI = 95.2 – 100%	95% CI – 95.14 – 100%	95% CI = 95.2 – 100%

Plasma – EDTA

Clinical Specificity (random donors)		Analytical Sensitivity (spiked samples)	
Cadaveric	Living	Cadaveric	Living
84/84+0 = 100%	76/76+0 = 100%	84/84+0 = 100%	76/76+0 = 100%
95% CI = 95.7 – 100%	95% CI = 95.26 – 100%	95% CI = 95.7 – 100%	95% CI = 95.26 – 100%

Conclusion:

The sensitivity and specificity for cadaveric donor specimens and living donor specimens are substantially equivalent.

Repeatability

Repeatability is defined as the variation in measurements taken by a single instrument on the same item and under the same conditions.

Repeatability testing was conducted at Arlington Scientific. The testing consisted of:

- Testing twenty (20) cadaveric samples prior to being spiked.
- Testing twenty (20) cadaveric samples spiked with a reactive specimen with a titer of 1:2 or 1:4
- Testing twenty (20) living-donor samples prior to being spiked.
- Testing twenty (20) living-donor samples spiked with a reactive specimen with a titer of 1:2 or 1:4
- Each sample was tested each day for six non-consecutive days by an operator with experience in performing the ASI RPR Test for Syphilis and operating the ASI Evolution.
- Each sample was tested with three different lots of carbon antigen.
- Each sample was evaluated for the degree of hemolysis. The amount of hemolysis in the sample ranged from none to a heavy degree.

The results of testing the cadaveric samples are contained in Tables 7 to 9:

Table 7

					Results					
					ASI Evolution ID# 5800-1022					
	Sample ID	Sample Type	Hemolysis	Titer	7/1/2020	7/6/2020	7/8/2020	7/10/2020	7/13/2020	7/15/2020
	Cadaveric Unspiked Samples – Carbon Antigen Lot CA9P02RRD									
1	30013647	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
2	30013615	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
3	30013646	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
4	30013663	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
5	10662892	Red Top	Moderate	N/A	NR	NR	NR	NR	NR	NR
6	10588533	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
7	20060904	Red Top	Moderate	N/A	NR	NR	NR	NR	NR	NR
8	10682077	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
9	10697670	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
10	10638866	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
11	10697669(2)	SST	None	N/A	NR	NR	NR	NR	NR	NR
12	10700530(2)	SST	Light	N/A	NR	NR	NR	NR	NR	NR
13	10670779(2)	SST	Heavy	N/A	NR	NR	NR	NR	NR	NR
14	10638858	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
15	10670781(2)	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
16	10619513	EDTA	Moderate	N/A	NR	NR	NR	NR	NR	NR
17	10638862	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
18	10670783	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR

19	10585950	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
20	10577232(2)	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
	Cadaveric Spiked Samples – Carbon Antigen Lot CA9P02RRD									
1	30013647	Red Top	Heavy	1:4	R	R	R	R	R	R
2	30013615	Red Top	None	1:2	R	R	R	R	R	R
3	30013646	Red Top	Light	1:4	R	R	R	R	R	R
4	30013663	Red Top	Heavy	1:4	R	R	R	R	R	R
5	10662892	Red Top	Moderate	1:2	R	R	R	R	R	R
6	10588533	Red Top	Heavy	1:2	R	R	R	R	R	R
7	20060904	Red Top	Moderate	1:2	R	R	R	R	R	R
8	10682077	SST	Moderate	1:4	R	R	R	R	R	R
9	10697670	SST	Moderate	1:2	R	R	R	R	R	R
10	10638866	SST	Moderate	1:2	R	R	R	R	R	R
11	10697669(2)	SST	None	1:4	R	R	R	R	R	R
12	10700530(2)	SST	Light	1:2	R	R	R	R	R	R
13	10670779(2)	SST	Heavy	1:4	R	R	R	R	R	R
14	10638858	EDTA	Light	1:2	R	R	R	R	R	R
15	10670781(2)	EDTA	Heavy	1:2	R	R	R	R	R	R
16	10619513	EDTA	Moderate	1:4	R	R	R	R	R	R
17	10638862	EDTA	Heavy	1:2	R	R	R	R	R	R
18	10670783	EDTA	Light	1:4	R	R	R	R	R	R
19	10585950	EDTA	Heavy	1:2	R	R	R	R	R	R
20	10577232(2)	EDTA	Light	1:4	R	R	R	R	R	R

Table 8

					Results					
					ASI Evolution ID# 5800-1022					
	Sample ID	Sample Type	Hemolysis	Titer	7/1/2020	7/6/2020	7/8/2020	7/10/2020	7/13/2020	7/15/2020
	Cadaveric Unspiked Samples – Carbon Antigen Lot CA9P19RA									
1	30013647	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
2	30013615	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
3	30013646	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
4	30013663	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
5	10662892	Red Top	Moderate	N/A	NR	NR	NR	NR	NR	NR
6	10588533	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
7	20060904	Red Top	Moderate	N/A	NR	NR	NR	NR	NR	NR
8	10682077	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
9	10697670	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
10	10638866	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
11	10697669(2)	SST	None	N/A	NR	NR	NR	NR	NR	NR
12	10700530(2)	SST	Light	N/A	NR	NR	NR	NR	NR	NR
13	10670779(2)	SST	Heavy	N/A	NR	NR	NR	NR	NR	NR
14	10638858	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
15	10670781(2)	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
16	10619513	EDTA	Moderate	N/A	NR	NR	NR	NR	NR	NR
17	10638862	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
18	10670783	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
19	10585950	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
20	10577232(2)	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
	Cadaveric Spiked Samples – Carbon Antigen Lot CA9P18RA									
1	30013647	Red Top	Heavy	1:4	R	R	R	R	R	R
2	30013615	Red Top	None	1:2	R	R	R	R	R	R
3	30013646	Red Top	Light	1:4	R	R	R	R	R	R
4	30013663	Red Top	Heavy	1:4	R	R	R	R	R	R
5	10662892	Red Top	Moderate	1:2	R	R	R	R	R	R
6	10588533	Red Top	Heavy	1:2	R	R	R	R	R	R
7	20060904	Red Top	Moderate	1:2	R	R	R	R	R	R
8	10682077	SST	Moderate	1:4	R	R	R	R	R	R
9	10697670	SST	Moderate	1:2	R	R	R	R	R	R
10	10638866	SST	Moderate	1:2	R	R	R	R	R	R
11	10697669(2)	SST	None	1:4	R	R	R	R	R	R
12	10700530(2)	SST	Light	1:2	R	R	R	R	R	R
13	10670779(2)	SST	Heavy	1:4	R	R	R	R	R	R
14	10638858	EDTA	Light	1:2	R	R	R	R	R	R
15	10670781(2)	EDTA	Heavy	1:2	R	R	R	R	R	R
16	10619513	EDTA	Moderate	1:4	R	R	R	R	R	R
17	10638862	EDTA	Heavy	1:2	R	R	R	R	R	R
18	10670783	EDTA	Light	1:4	R	R	R	R	R	R
19	10585950	EDTA	Heavy	1:2	R	R	R	R	R	R
20	10577232(2)	EDTA	Light	1:4	R	R	R	R	R	R

Table 9

					Results					
					ASI Evolution ID# 5800-1022					
	Sample ID	Sample Type	Hemolysis	Titer	7/1/2020	7/6/2020	7/8/2020	7/10/2020	7/13/2020	7/15/2020
	Cadaveric Unspiked Samples – Carbon Antigen Lot CA0A03RZZ									
1	30013647	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
2	30013615	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
3	30013646	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
4	30013663	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
5	10662892	Red Top	Moderate	N/A	NR	NR	NR	NR	NR	NR
6	10588533	Red Top	Heavy	N/A	NR	NR	NR	NR	NR	NR
7	20060904	Red Top	Moderate	N/A	NR	NR	NR	NR	NR	NR
8	10682077	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
9	10697670	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
10	10638866	SST	Moderate	N/A	NR	NR	NR	NR	NR	NR
11	10697669(2)	SST	None	N/A	NR	NR	NR	NR	NR	NR
12	10700530(2)	SST	Light	N/A	NR	NR	NR	NR	NR	NR
13	10670779(2)	SST	Heavy	N/A	NR	NR	NR	NR	NR	NR
14	10638858	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
15	10670781(2)	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
16	10619513	EDTA	Moderate	N/A	NR	NR	NR	NR	NR	NR
17	10638862	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
18	10670783	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
19	10585950	EDTA	Heavy	N/A	NR	NR	NR	NR	NR	NR
20	10577232(2)	EDTA	Light	N/A	NR	NR	NR	NR	NR	NR
	Cadaveric Spiked Samples – Carbon Antigen Lot CA0A03RZZ									
1	30013647	Red Top	Heavy	1:4	R	R	R	R	R	R
2	30013615	Red Top	None	1:2	R	R	R	R	R	R
3	30013646	Red Top	Light	1:4	R	R	R	R	R	R
4	30013663	Red Top	Heavy	1:4	R	R	R	R	R	R
5	10662892	Red Top	Moderate	1:2	R	R	R	R	R	R
6	10588533	Red Top	Heavy	1:2	R	R	R	R	R	R
7	20060904	Red Top	Moderate	1:2	R	R	R	R	R	R
8	10682077	SST	Moderate	1:4	R	R	R	R	R	R
9	10697670	SST	Moderate	1:2	R	R	R	R	R	R
10	10638866	SST	Moderate	1:2	R	R	R	R	R	R
11	10697669(2)	SST	None	1:4	R	R	R	R	R	R
12	10700530(2)	SST	Light	1:2	R	R	R	R	R	R
13	10670779(2)	SST	Heavy	1:4	R	R	R	R	R	R
14	10638858	EDTA	Light	1:2	R	R	R	R	R	R
15	10670781(2)	EDTA	Heavy	1:2	R	R	R	R	R	R
16	10619513	EDTA	Moderate	1:4	R	R	R	R	R	R
17	10638862	EDTA	Heavy	1:2	R	R	R	R	R	R
18	10670783	EDTA	Light	1:4	R	R	R	R	R	R
19	10585950	EDTA	Heavy	1:2	R	R	R	R	R	R
20	10577232(2)	EDTA	Light	1:4	R	R	R	R	R	R

The results of testing the living-donor samples are contained in Tables 10 to 12:

Table 10

					Results					
					ASI Evolution ID# 5800-1022					
	Sample ID	Sample Type	Hemolysis	Titer	7/1/2020	7/6/2020	7/8/2020	7/10/2020	7/13/2020	7/15/2020
	Living Unspiked Samples – Carbon An igen Lot CA9P02RRD									
1	10662622	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
2	30033734	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
3	10667443	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
4	10682793	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
5	10680285	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
6	10682493	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
7	10683027	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
8	10542608	SST	None	N/A	NR	NR	NR	NR	NR	NR
9	10542614	SST	None	N/A	NR	NR	NR	NR	NR	NR
10	10615078	SST	Light	N/A	NR	NR	NR	NR	NR	NR
11	10542606	SST	None	N/A	NR	NR	NR	NR	NR	NR
12	10671043	SST	None	N/A	NR	NR	NR	NR	NR	NR
13	10542603	SST	None	N/A	NR	NR	NR	NR	NR	NR
14	10528444	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
15	10579337(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
16	10683025(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
17	10680289(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
18	10681600(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
19	10662622(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
20	10667443(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
	Living Spiked Samples – Carbon Antigen Lot CA9P02RRD									

1	10662622	Red Top	None	1:4	R	R	R	R	R	R
2	30033734	Red Top	None	1:2	R	R	R	R	R	R
3	10667443	Red Top	Light	1:2	R	R	R	R	R	R
4	10682793	Red Top	None	1:4	R	R	R	R	R	R
5	10680285	Red Top	None	1:2	R	R	R	R	R	R
6	10682493	Red Top	None	1:4	R	R	R	R	R	R
7	10683027	Red Top	Light	1:2	R	R	R	R	R	R
8	10542608	SST	None	1:2	R	R	R	R	R	R
9	10542614	SST	None	1:2	R	R	R	R	R	R
10	10615078	SST	Light	1:4	R	R	R	R	R	R
11	10542606	SST	None	1:4	R	R	R	R	R	R
12	10671043	SST	None	1:2	R	R	R	R	R	R
13	10542603	SST	None	1:4	R	R	R	R	R	R
14	10528444	EDTA	None	1:4	R	R	R	R	R	R
15	10579337(2)	EDTA	None	1:2	R	R	R	R	R	R
16	10683025(2)	EDTA	None	1:4	R	R	R	R	R	R
17	10680289(2)	EDTA	None	1:2	R	R	R	R	R	R
18	10681600(2)	EDTA	None	1:4	R	R	R	R	R	R
19	10662622(2)	EDTA	None	1:2	R	R	R	R	R	R
20	10667443(2)	EDTA	None	1:2	R	R	R	R	R	R

Table 11

					Results					
					ASI Evolution ID# 5800-1022					
	Sample ID	Sample Type	Hemolysis	Titer	7/1/2020	7/6/2020	7/8/2020	7/10/2020	7/13/2020	7/15/2020
	Living Unspiked Samples – Carbon Antigen Lot CA9P18RA									
1	10662622	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
2	30033734	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
3	10667443	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
4	10682793	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
5	10680285	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
6	10682493	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
7	10683027	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
8	10542608	SST	None	N/A	NR	NR	NR	NR	NR	NR
9	10542614	SST	None	N/A	NR	NR	NR	NR	NR	NR
10	10615078	SST	Light	N/A	NR	NR	NR	NR	NR	NR
11	10542606	SST	None	N/A	NR	NR	NR	NR	NR	NR
12	10671043	SST	None	N/A	NR	NR	NR	NR	NR	NR
13	10542603	SST	None	N/A	NR	NR	NR	NR	NR	NR
14	10528444	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
15	10579337(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
16	10683025(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
17	10680289(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
18	10681600(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
19	10662622(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
20	10667443(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
	Living Spiked Samples – Carbon Antigen Lot CA9P18RA									
1	10662622	Red Top	None	1:4	R	R	R	R	R	R
2	30033734	Red Top	None	1:2	R	R	R	R	R	R
3	10667443	Red Top	Light	1:2	R	R	R	R	R	R
4	10682793	Red Top	None	1:4	R	R	R	R	R	R
5	10680285	Red Top	None	1:2	R	R	R	R	R	R
6	10682493	Red Top	None	1:4	R	R	R	R	R	R
7	10683027	Red Top	Light	1:2	R	R	R	R	R	R
8	10542608	SST	None	1:2	R	R	R	R	R	R
9	10542614	SST	None	1:2	R	R	R	R	R	R
10	10615078	SST	Light	1:4	R	R	R	R	R	R
11	10542606	SST	None	1:4	R	R	R	R	R	R
12	10671043	SST	None	1:2	R	R	R	R	R	R
13	10542603	SST	None	1:4	R	R	R	R	R	R
14	10528444	EDTA	None	1:4	R	R	R	R	R	R
15	10579337(2)	EDTA	None	1:2	R	R	R	R	R	R
16	10683025(2)	EDTA	None	1:4	R	R	R	R	R	R
17	10680289(2)	EDTA	None	1:2	R	R	R	R	R	R
18	10681600(2)	EDTA	None	1:4	R	R	R	R	R	R
19	10662622(2)	EDTA	None	1:2	R	R	R	R	R	R
20	10667443(2)	EDTA	None	1:2	R	R	R	R	R	R

Table 12

					Results					
					ASI Evolution ID# 5800-1022					
	Sample ID	Sample Type	Hemolysis	Titer	7/1/2020	7/6/2020	7/8/2020	7/10/2020	7/13/2020	7/15/2020
	Living Unspiked Samples – Carbon Antigen Lot CA0A03RZZ									
1	10662622	Red Top	None	N/A	NR	NR	NR	NR	NR	NR

2	30033734	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
3	10667443	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
4	10682793	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
5	10680285	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
6	10682493	Red Top	None	N/A	NR	NR	NR	NR	NR	NR
7	10683027	Red Top	Light	N/A	NR	NR	NR	NR	NR	NR
8	10542608	SST	None	N/A	NR	NR	NR	NR	NR	NR
9	10542614	SST	None	N/A	NR	NR	NR	NR	NR	NR
10	10615078	SST	Light	N/A	NR	NR	NR	NR	NR	NR
11	10542606	SST	None	N/A	NR	NR	NR	NR	NR	NR
12	10671043	SST	None	N/A	NR	NR	NR	NR	NR	NR
13	10542603	SST	None	N/A	NR	NR	NR	NR	NR	NR
14	10528444	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
15	10579337(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
16	10683025(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
17	10680289(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
18	10681600(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
19	10662622(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
20	10667443(2)	EDTA	None	N/A	NR	NR	NR	NR	NR	NR
	Living Spiked Samples – Carbon Antigen Lot CA0A03RZZ									
1	10662622	Red Top	None	1:4	R	R	R	R	R	R
2	30033734	Red Top	None	1:2	R	R	R	R	R	R
3	10667443	Red Top	Light	1:2	R	R	R	R	R	R
4	10682793	Red Top	None	1:4	R	R	R	R	R	R
5	10680285	Red Top	None	1:2	R	R	R	R	R	R
6	10682493	Red Top	None	1:4	R	R	R	R	R	R
7	10683027	Red Top	Light	1:2	R	R	R	R	R	R
8	10542608	SST	None	1:2	R	R	R	R	R	R
9	10542614	SST	None	1:2	R	R	R	R	R	R
10	10615078	SST	Light	1:4	R	R	R	R	R	R
11	10542606	SST	None	1:4	R	R	R	R	R	R
12	10671043	SST	None	1:2	R	R	R	R	R	R
13	10542603	SST	None	1:4	R	R	R	R	R	R
14	10528444	EDTA	None	1:4	R	R	R	R	R	R
15	10579337(2)	EDTA	None	1:2	R	R	R	R	R	R
16	10683025(2)	EDTA	None	1:4	R	R	R	R	R	R
17	10680289(2)	EDTA	None	1:2	R	R	R	R	R	R
18	10681600(2)	EDTA	None	1:4	R	R	R	R	R	R
19	10662622(2)	EDTA	None	1:2	R	R	R	R	R	R
20	10667443(2)	EDTA	None	1:2	R	R	R	R	R	R

There was 100% agreement between the results of all testing.

Using the Fisher Exact Test, a p-value can be calculated comparing cadaveric and living donor samples.

Table 13. Repeatability Results

		ASI Evolution Results for Cadaveric Donor Samples		
		Reactive	Nonreactive	Total
ASI Evolution Results for Living Donor Samples	Reactive	20	0	20
	Nonreactive	0	20	20
	Total	20	20	40

The Fisher exact statistic value is <0.00001. The result is significant at p <0.05.

The data shows a very high degree of repeatability.

Reproducibility

Reproducibility is defined as the variation in measurements taken by multiple instruments on the same item and under the same conditions.

The interpretation of 20 samples using the ASI RPR Test for Syphilis and the ASI Evolution were evaluated for reactivity. The testing requirements were as follows:

1. Three different ASI Evolutions with the new algorithm were used for testing.
2. Ten cadaveric and ten living donor samples were used.
3. Each sample was tested 19 times on each instrument.
4. The same samples and reagents were used on all three instruments
5. Each sample was evaluated for the degree of hemolysis. The amount of hemolysis in the samples ranged from none to a heavy degree.

A total of 20 samples (all collected in red top tubes) were evaluated to determine reproducibility of reactivity between the three instruments. Of the 20 samples, 14 were reactive and 6 were nonreactive. The reactive samples had titers of 1:2 (8 samples), 1:4 (2 sample), 1:8 (2 sample) and 1:16 (2 sample). Each of the 20 samples was repeated 19 times to evaluate the reactivity using the ASI Evolution. An aliquot of the same sample was dispensed into 19 tubes. All 19 tubes were placed into the ASI Evolution and the run was performed. Refer to Table 14.

Table 14

	Sample	Expected	Results						% Agreement
	Sample ID	Titer	Evolution 1		Evolution 2		Evolution 3		
Cadaveric Donor Samples									
1	20071005	1:2	19/19	R	19/19	R	19/19	R	100%
2	20070804	1:8	19/19	R	19/19	R	19/19	R	100%
3	20070705	1:4	19/19	R	19/19	R	19/19	R	100%
4	20070806	1:2	19/19	R	19/19	R	19/19	R	100%
5	20070504	1:2	19/19	R	19/19	R	19/19	R	100%
6	20062806	1:2	19/19	R	19/19	R	19/19	R	100%
7	20061302	1:16	19/19	R	19/19	R	19/19	R	100%
8	10576054	NR	19/19	NR	19/19	NR	19/19	NR	100%
9	20060901	NR	19/19	NR	19/19	NR	19/19	NR	100%
10	20060806	NR	19/19	NR	19/19	NR	19/19	NR	100%
Living Donor Samples									
1	20060604	1:16	19/19	R	19/19	R	19/19	R	100%
2	100558702(2)	1:8	19/19	R	19/19	R	19/19	R	100%
3	10682291	1:2	19/19	R	19/19	R	19/19	R	100%
4	10663420	1:4	19/19	R	19/19	R	19/19	R	100%
5	10681685	1:2	19/19	R	19/19	R	19/19	R	100%
6	10630627	1:2	19/19	R	19/19	R	19/19	R	100%
7	10666753	1:2	19/19	R	19/19	R	19/19	R	100%
8	10703825	NR	19/19	NR	19/19	NR	19/19	NR	100%
9	10668273	NR	19/19	NR	19/19	NR	19/19	NR	100%
10	10683282	NR	19/19	NR	19/19	NR	19/19	NR	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

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.