Subject/Title: **ASI TPHA TEST KIT**		Doc#: 6004-980 NCCLS
Effective Date: 02/03	Supersedes Revision/Date:	Revision: 02/03
Prepared by: ASI	QA Approval by:	Copy/Dept.:

FOR IN VITRO DIAGNOSTIC USE

Cat. No.	9802000	2000 Tests
	9804000	4000 Tests
	9806000	6000 Tests

1 **INTENDED USE:** The **ASI TPHA TEST** is a qualitative microhemagglutination test for the presence of IgG and IgM antibodies to *Treponema pallidum*, the causative agent for syphilis, in human serum and EDTA plasma. It is formulated for use on the Olympus PK7200™ Automated Microplate System. Serum is the sample of choice and any repeat or confirmatory testing must be done on serum. This test is intended for screening of blood donors only.

2 **SUMMARY AND EXPLANATION:** The identification of antibody to *Treponema pallidum* aids in the diagnosis of syphilis. The first serological test for syphilis was developed by Wasserman in 1906. It was a nontreponemal complement fixation test that detected both immunoglobulin G (IgG) and M (IgM) anti-lipid antibodies formed by the host in response to lipoidal materials released by damaged host cells or to lipid from the treponeme itself. Either because of the lipid nature of the antigen or some unusual property of the antibodies formed, the antigen-antibody reaction does not result in agglutination or precipitation but rather flocculation occurs[1]. If a sample is found to be reactive, then an additional test on serum must be done to rule out false positives.

Hemagglutination (TPHA) tests for *Treponema pallidum* have gained wide acceptance for use as a confirmatory test since the mid 1960's[2,3,4]. Automation has enhanced the value of the test by reducing the amount of time and labor needed to perform the assay[5]. The **ASI TPHA TEST** is formulated as a reagent system for use on the Olympus PK7200™ Automated Microplate System. For complete directions on use of the Olympus PK7200™ system, refer to the Operations Manual provided by the manufacturer.

3 **PRINCIPLE OF THE PROCEDURE:** The **ASI TPHA TEST** is a treponemal test for the serologic detection of antibodies to *T. pallidum*. The test is a passive hemagglutination assay based on the flocculation of avian erythrocytes sensitized with *T. pallidum* antigen by antibodies found in the patient's serum or plasma.

The test sample is diluted in absorbing diluent to remove possible cross-reacting heterophile antibody and to remove, block, or absorb potentially cross-reacting, nonpathogenic treponemal antibodies. Sera containing antibodies to *T. pallidum* react with chicken erythrocytes sensitized with sonicated *T. pallidum*, Nichols strain (the antigen), to form a smooth mat of agglutinated cells in the microtiter tray well. If antibodies are not present the cells settle to the bottom of the tray well, forming a compact button of unagglutinated cells[1]. The Olympus PK7200™ reads the test wells and differentiates between the patterns of agglutinated and unagglutinated cells.

4 **REAGENTS**

4.1 **TPHA TEST CELLS** - Preserved chicken erythrocytes, treated with tannic acid and coated with antigens to *T. pallidum.* The cells are washed and suspended in a medium containing: sorbent, rabbit serum and bovine serum albumin (USA source), 0.002% Gentamycin sulphate and 0.1% sodium azide as preservatives, and Tween 20 surfactant in a phosphate-buffered saline solution. Mix well to resuspend the cells before using. Expiration: 12 months after date of manufacture when stored at 2–8ºC.

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4.2 **TPHA SAMPLE DILUENT** - Phosphate buffered saline solution containing absorbers (used to remove possible cross-reacting heterophile antibodies), ox stroma, rabbit serum, and Tween 20 surfactant in a phosphate-buffered saline solution preserved with 0.1% sodium azide. Expiration: 12 months after date of manufacture when stored at 2–8ºC.

4.3 **TPHA REACTIVE CONTROL** - Human defibrinated plasma, as required for titer, in a phosphate-buffered saline solution preserved with 0.1% sodium azide. Expiration: 12 months after date of manufacture when stored at 2–8ºC.

4.4 **TPHA NON-REACTIVE CONTROL** - Human defibrinated plasma in a phosphate-buffered saline solution preserved with 0.1% sodium azide. Expiration: 12 months after date of manufacture when stored at 2–8ºC.

5 WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

5.1 **ASI TPHA TEST** CELLS, DILUENT and CONTROLS 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.

5.2 **ASI TPHA TEST** CONTROLS contain human plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be non-reactive. 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. REACTIVE AND Non-reactive CONTROL material should be handled in the same fashion as donor samples. The CDC/NIH Health Manual “Biosafety in Microbiological Laboratories” describes how these materials should be handled in accordance with Good Laboratory Practice[6].

5.3 The microplates must be clean before use. Inadequate washing can adversely affect a test result by causing a false positive or false negative reaction. Instructions for microplate washing are in the Olympus PK7200™ Standard Operating Procedure Manual and should be carefully followed.

5.4 All reagents should be brought to room temperature (15-30º C) prior to use on the analyzer.

5.5 Carryover between specimens is a potential source of interference.

5.6 If the Olympus PK7200™ fails to add sample to the reaction well, a false negative result will occur.

5.7 Do not pipet by mouth.

5.8 Do not smoke, eat, drink or apply cosmetics in areas where plasma/serum samples are handled.

5.9 Any cuts, abrasions or other skin lesions should be suitably protected.

6 STORAGE INSTRUCTIONS:

Store the kit contents at 2–8ºC in an upright position. Do not freeze reagents. The contents of opened containers are stable for 12 months after the date of manufacture. Do not use reagents after the expiration date indicated on the container.

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8 INDICATIONS OF DETERIORATION

8.1 Precipitation or turbidity in the CONTROLS or DILUENT is indicative of deterioration and the component should not be used.

8.2 Hemolysis of the TPHA TEST CELL reagent is indicative of deterioration and the component should not be used.

9 INSTRUMENTATION

The ASI TPHA test system is formulated for use with the Olympus PK7200™ Automated Microplate System using the same parameters and threshold settings that are used for the Olympus Fujirebio reagents. The PK7200™ manufacturer's instructions regarding installation, operation, calibration, precautions and troubleshooting should be closely followed. Instrument settings are approximate and some variance can occur from instrument to instrument. If you need technical assistance call ASI technical support (800) 654-0146.

10 SPECIMEN COLLECTION AND STORAGE

10.1 Use serum or EDTA (1.5 - 2.2 mg/mL) plasma for specimens. Serum is preferred. Only serum or plasma stored at 2–8º C may be **tested up to seven days after collection**. Specimens should be maintained at 2–8º C during transport and packaged to maintain the integrity of the specimens in accordance with the US Department of Transportation (USDOT) Dangerous Goods Shipping Regulations, and other applicable laws and standards. Specimens should be brought to room temperature (15-30º C) before testing.

10.2 Specimens from pleural fluid, saliva, cadaveric samples or non human species are not acceptable for testing.

10.3 Samples should be free from bacterial contamination or hemolysis.

10.4 Specimens should not contain particulate matter. If necessary before testing,centrifuge the specimens at a force sufficient to sediment cellular components.

10.5 Samples are unacceptable if they contain greater than the following amounts of:

Free hemoglobin	1000 mg/dl
Phospholipids	1000 mg/dl
Total bilirubin	20 mg/dl

10.6 If a delay of more than 7 days is anticipated before testing, freeze the specimen at -20º C or below. Frozen specimens should be brought to room temperature (15–30ºC) and mixed thoroughly before testing. Do not repeatedly freeze and thaw specimens.

10.7 Heat-treated specimens and plasma using sodium citrate or heparin as anticoagulants should not be used with the **ASI TPHA TEST** reagents.

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11 **MATERIALS PROVIDED** (See quantities for each kit size in the REAGENTS Section on page 2.)

11.1 TPHA TEST CELLS
11.2 TPHA SAMPLE DILUENT
11.3 TPHA REACTIVE CONTROL
11.4 TPHA Non-reactive CONTROL

12 **ADDITIONAL MATERIALS REQUIRED**

12.1 Olympus PK7200™ Automated Microplate System
12.2 Olympus P3-Microtitration Plate™

13 **HANDLING AND PROCEDURAL NOTES**

13.1 In order to obtain reliable and consistent results, the instructions in this package insert must be strictly followed. Do not modify the handling or storage conditions for the reagents or samples.

13.2 The microplates must be clean before use. Inadequate washing may cause false negative or false positive results. Instructions for microplate washing are in the Olympus PK7200™ Standard Operating Procedure Manual and should be carefully followed.

13.3 Do not use past the expiration date indicated on the kit.

13.4 Do not use reagents from one kit with reagents from a kit with a different lot number.

14 **TEST PROCEDURE**

14.1 Bring test reagents and specimens to room temperature, (15 - 30º C).

14.2 Programming of the software, setting and validating of operating parameters should be done in accordance with the Olympus PK7200™ Operator's Manual. The **ASI TPHA Test** reagents are designed and intended for use on the PK7200™ Automated Microplate System using the same parameters and threshold settings that are used for the Olympus Fujirebio reagents. Recommended instrument and threshold settings are shown in Table 1.

14.3 Connect the PK7200™ sample diluent dispenser line to the ASI TPHA SAMPLE DILUENT bottle. The volume of diluent dispensed is controlled by the PK7200™ settings and software. Remove the G Stroke pins for the diluent lines and press the PREP button to start the PREP cycle. After the cycle is complete, replace the G Stroke pins. Be sure that the pin marked "G 0.25" is placed under the syringe that will be used to aspirate the sample diluent. ALTERNATIVELY, a black rack of tubes filled with saline can be processed at the beginning of the run, eliminating the need to remove and replace the G Stroke pins.

14.4 Press the DIAG button to eliminate bubbles in the sample probes.

14.5 Re-suspend test cells by thoroughly mixing (by inverting to ensure homogeneity) and add to the PK7200™ reagent reservoir. Ensure suspension throughout processing by the use of the mixing comb. Do not allow the erythrocytes to settle out of the suspension.

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14.6 Thirty-seven (37) ml of cells is sufficient for 1050 tests. Any surplus test cells should be decanted into a bottle and stored refrigerated (2-8ºC) for future use prior to the expiration date.

14.7 The Reactive and Non-reactive Controls provided with each kit of reagents should be run at the beginning and the end of each batch. The use of the controls is recommended to ensure proper kit performance.

14.8 Proceed with the analysis as described in the Olympus PK7200™ Operator's Manual.

Table 1 ASSAY PROTOCOL - Instrument Settings for PK7200™

Recommended Volumes for PK7200™			
REAGENT NAME	TPHA	REAGENT VOLUME	35 µl
DILUENT NAME	SAMPLE DILUENT	DILUENT VOLUME	250 µl
SAMPLE	PLASMA/SERUM	SAMPLE VOLUME	40 µl
SAMPLE/DILUENT RATIO	160 µl/1000 µl	DILUTED SAMPLE VOLUME	15 µl
FINAL PLASMA/SERUM DILUTION	1/24		
Recommended Threshold Settings for the PK7200™			
SPC THRESHOLD	Low 16 High 16		
P / C THRESHOLD	(+) 41 (-) 26		
LIA THRESHOLD	(+) 240 (-) 100		
LIA SELECTION	5		
BG / C LIMIT	Low		
Recommended Additional Settings			
REACTION TIME	60 min		
REACTION TEMPERATURE	28 - 32º C		
PLATE WELL	16		
DECISION LOGIC SET	+/-		
P / C THRESHOLD	: (+) 41 (-) 26		
LIA THRESHOLD	: (+) 240 (-) 100		
LIMIT SET			
BG / C LIMIT	: Low		
LIA SELECTION	: 5		

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15 QUALITY CONTROL

15.1 The controls must be run at the beginning and end of each batch of samples. (Maximum batch size of 357 samples.) Controls must also be run after the addition of reagents, and after an interruption or delays in processing.

15.2 The Reactive control should give a clear positive result.

15.3 The Non-reactive control should give a clear negative result.

15.4 Reactive and Non-reactive controls should be tested again if a delay occurs that stops test cell mixing.

15.5 The Olympus PK7200™ determines the presence of antibodies to *Treponema pallidum* with a camera which analyses the well images and differentiates between agglutinated and non-agglutinated patterns. As soon as possible, results should be reviewed by visual judgment of the reaction pattern in each cell.

16 INTERPRETATION OF RESULTS

16.1 If the controls do not give the expected result, all assays performed in that batch are invalid and must be tested again.

16.2 Any sample with disagreement between the automated and visual interpretations must receive additional testing in accordance with the Olympus PK7200™ Standard Operating Procedure Manual.

16.3 Sharpness of the edge of the cell button is the most significant indicator of agglutination (SPC column in Table 2).

16.3.1 A positive SPC result combined with either a positive or indeterminate LIA or P/C result is interpreted as a positive reaction.

16.3.2 A positive SPC result combined with a negative LIA or P/C result is interpreted as indeterminate.

16.3.3 A negative SPC result combined with either a negative or indeterminate LIA or P/C result is interpreted as a negative reaction.

16.3.4 A negative SPC result combined with a positive LIA or P/C result is interpreted as indeterminate.

Test Cells

Reactive: A homogeneous layer of cells.

Indeterminate: Cell pattern shows a distinctly open center (- or **?** In Table 2).

Non-reactive: Cells settled to a compact dense button, surrounded by a clear zone.

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A sample reported as non-reactive on initial screening is considered to be non-reactive for antibodies to *T. pallidum* and needs no further testing.

An EDTA plasma specimen that is reactive or indeterminate (?) on initial screening with the **ASI TPHA Test** reagents is considered initially reactive by the **ASI TPHA Test**, but prior to interpretation, the test should be repeated in duplicate using a serum specimen from the same draw. The duplicate tests must occur in the same run. If either duplicate is reactive or indeterminate, the specimen is to be interpreted as repeatedly reactive for antibodies to *T. Pallidum* by the criteria of the **ASI TPHA Test**. Initially reactive plasma specimens that are negative in both of the duplicate retests are considered non-reactive by the criteria of the **ASI TPHA Test**.

TABLE 2 TEST INTERPRETATION FROM CHANNEL RESULTS

KEY	TEST INTERPRETATION	CHANNEL RESULTS SPC	LIA	P/C
SPC: Sharpness of the edge of the cell button	Reactive	**+**	**+** or **?**	**+** or **?**
Threshold: Low 16, High 16	Non-reactive	-	- or **?**	- or **?**
LIA: Quantity of cells in center of the well	Indeterminate	**+**	-	-
Threshold: (-) Limit 100, (**+**) Limit 240	Indeterminate	**+**	-	**+**
P/C: Ratio of the average light transmittance of the peripheral and central values	Indeterminate	**+**	**+**	-
Threshold: (-) Limit 26, (**+**) Limit 41	Indeterminate	-	**+**	**+**
	Indeterminate	-	**+**	-
	Indeterminate	-	-	**+**
	Indeterminate	**?**	**+**, -, or **?**	**+**, -, or **?**

17 LIMITATIONS OF THE PROCEDURE

17.1 Serum must be used for any repeat or confirmatory testing on any indeterminate or reactive plasma.

17.2 Carryover between specimens is a possible source of interference.

17.3 If the PK7200™ fails to add sample to the reaction well, a false negative result can occur.

17.4 A diagnosis of syphilis should be made on the basis of a careful history and physical examination together with laboratory results.

17.5 The **ASI TPHA Test** kit is for use only in screening blood donors and has not been evaluated for use other than blood bank screening.

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18 **EXPECTED VALUES:** Specimens found to be reactive on the Olympus PK7200™ System using the **ASI TPHA Test Reagents** are considered to be reactive for IgG and/or IgM antibodies to *T. Pallidum*. Reactive results may indicate an active, past, or successfully treated infection. A diagnosis should be made with a careful history of the patient and a physical examination as well as pertinent laboratory results.

Studies performed on 780 random blood donors have shown the initial plasma reactive rate to be 0.13 percent. The repeat reactive rate is also shown to be 0.13 percent (see Table 3). Laboratories may experience a different initial and repeat reactive rate depending on the geographical area.

19 **REPEAT AND CONFIRMATORY TESTING**: Random blood donor specimens were tested on the Olympus PK7200™ Automated Microplate System using **ASI TPHA Test** reagents tested in parallel with Olympus PK™ TP reagents. A total of 2758 specimens were tested at three separate laboratories. Initial testing was done on plasma samples, and those with reactive or indeterminate results were tested again using serum samples from the same donors. Specimens that were repeat reactive or indeterminate were confirmed with the MHATP and FTA-ABS tests.

Table 3 Repeat and Confirmatory Testing of Initially Reactive Specimens

PK7200™ System Results		Number of Specimens Represented By Each Combination of TP System Results		MHATP and FTA-ABS Confirmation Results	
ASI TPHA Test Reagent	Olympus Reagent	Initial Test (Plasma)	Repeat Test (Serum)	Reactive	Non-reactive
Non-reactive	Non-reactive	2286	2288		
Non-reactive	Reactive	4	2	0	2
Reactive	Non-reactive	0	0	0	0
Reactive	Reactive	3	3	3	0
Totals		2293	2293		
ASI Reactive Rate		0.13%	0.13%		
Olympus Reactive Rate		0.30%	0.22%		

Note: This data is for the 2293 unknown specimens. It does not include the 355 known specimens that are included in other testing summaries.

20 **SPECIFIC PERFORMANCE CHARACTERISTICS**

20.1 The **ASI TPHA Test** shows a 99.87% correlation to the Olympus PK™ TP System.

20.2 Run-to-run precision is >99%. Within run precision is >99%.

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Parallel Test With Olympus PK™ TP System
COMPOSITE PERFORMANCE RESULTS (3 TEST SITES)

Table 4 **Initial (# 2-Day) Specimens—2758 Samples**

		ASI TPHA Test Reagent	
		Reactive	Non-reactive
Olympus Reagent	Reactive	417[1]	4[2]
	Non-reactive	0	2337

[1] All reagents identified all 338 known reactive samples and 3 unknown reactive samples. Confirmatory testing of the three unknown specimens were reactive by MHATP and FTA-ABS methods.

[2] The Olympus reagents identified 4 specimens as reactive which were non-reactive with the ASI reagents. Repeat tests using the Olympus reagent were reactive for two specimens and non-reactive for the other two specimens. Confirmatory testing was performed on the specimens that were repeat reactive and were FTA-ABS non-reactive.

An aging study, with both lots of ASI reagents only, was also performed using 862 EDTA plasma samples from the parallel study that were non-reactive in the initial test, and two (2) samples that were initially reactive for a total of 864 samples. The samples were tested on day 2 or 3 and day 7 post collection. Results are displayed in Table 5 and Table 6.

Table 5 **Day 2 or 3 Testing—374 Samples**

		Day 2 or 3 Specimens	
		Reactive	Non-reactive
Initial Results	Reactive	2	0
	Non-reactive	1[1]	861

[1] One sample that had initially tested non-reactive tested reactive at 48 hours. This same sample subsequently tested non-reactive at 7 days.

Table 6 **Day 7 Testing—374 Samples**

Day 2 or 3 Results	Seven Day-Old Samples: Reactive	Seven Day-Old Samples: Non-reactive
Reactive	2	1[1]
Non-reactive	0	861

[1] One sample tested non-reactive which had tested reactive at 48 hours and non-reactive on the initial test.

21 **Test Performance Characteristics**

21.1 **Accuracy:** **ASI TPHA Test** detected 338 of 338 known reactive samples and 17 of 17 non-reactive samples for 100% accuracy, and identified one reactive sample among the random unknown samples. The confirmatory testing of the reactive sample was also reactive.

The predicate device detected 338 of 338 known reactive samples and 17 of 17 non-reactive samples for 100% accuracy, and identified two reactive unknowns, one of which was confirmed reactive where as the other was non-reactive on repeat testing.

21.2 **Correlation:** Overall correlation with Olympus PK™ TP System is >99%

21.3 **Precision:** Run-to-run precision is >99%
Within run precision is >99%

22 **REPRODUCIBILITY**: The reproducibility of the **ASI TPHA Test** (Reagents) was evaluated at the three blood processing laboratories. One lab tested 130 and another 362 random samples on days 1, 3 and 7; another lab tested 369 random samples on days 1, 2 and 7. The results are summarized in Table 7.

Reproducibility was also evaluated at the three blood processing laboratories using 55 samples of known reactivity and both the same lot of ASI reagents and three separate lots of ASI test reagents. The results are summarized in Table 8.

Table 7 **Reproducibility of Test Results**

Test Results	Number of Tests Day 1	Number of Tests Day 2 or 3	Number of Tests Day 7
Reactive	2	2	2
Non-reactive	862	862	862
Total	864	864	864

- Two specimens were reactive each day of the test, confirmed by MHATP and FTA-ABS.

Testing at three laboratories using both the same lot of reagent and three different lots of reagent produced the same result in showing equivalence to the predicate reagents and consistency from day to day up to the seven day test.

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Table 8 **Reproducibility of Test Results of Known Specimens**

Test Results	Site A	Site B	Site C
Reactive (38)	38	38	38
Non-reactive (17)	17	17	17
Total (55)	55	55	55

Results from all sites produced the expected results. The fact that each of the three sites had the same lot of reagents and the same 55 samples and were able tho produce the same results, shows within lot reproducibility. The fact that each site had three separate lots of ASI reagents and the same 55 samples were able to produce the same results, shows lot to lot reproducibility.

22 **Test Sensitivity**

A comparison of the **ASI TPHA Test** reagents tested in parallel with Olympus PK™ TP reagents using the Olympus PK7200™ Automated Microplate System was done using 200 specimens from syphilitic individuals who had been previously characterized as primary, secondary, tertiary, both treated and untreated. Another 200 specimens that had been clinically diagnosed as having syphilis, but had been uncharacterized as to the stage of the disease were also used. The characterized samples were tested in two studies, 100 specimens were tested at the National Blood Services in North London, England and the other 100 specimens were tested at Gulf Coast Regional Blood Center in Houston, Texas along with the uncharacterized specimens. The results of both studies are summarized in Table 4-20 and Table 4-21. All samples are FTA-ABS positive.

Table 9 **TEST SENSITIVITY**

Syphilis Category	Number	Number Reactive		
		ASI TPHA	Olympus PK TP™	FTA-ABS
Primary				
Untreated	6	6	6	6
Treated	5	5	5	5
Unknown	75	75	75	75
Secondary				
Untreated	2	2	2	2
Treated	5	5	5	5
Unknown	48	48	48	48
Tertiary				
Untreated	1	1	1	1
Treated	14	14	14	14
Unknown	44	44	44	44
Uncharacterized	200	200	200	200
Total	400	400	400	400
Clinical Sensitivity		100%	100%	100%

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Table 10 SENSITIVITY OF ASI TPHA TEST ACCORDING TO DISEASE AND TREATMENT STAGE

	Number	Number Reactive		Sensitivity	
		ASI TPHA	Olympus PK TP™	ASI TPHA	Olympus PK TP™
Primary	86	86	86	100%	100%
Secondary	55	55	55	100%	100%
Tertiary	59	59	59	100%	100%
Untreated	9	9	9	100%	100%
Treated	24	24	24	100%	100%
Unknown	167	167	167	100%	100%

23 TEST SPECIFICITY

Comparison of test results with the **ASI TPHA Test** reagents used on the Olympus PK7200™ instrument with RPR test results on specimens with potentially interfering substances. (See Table 11)

Table 11 TEST SPECIFICITY

Specimen Category	Number of Samples	PK7200™ Results	FTA-ABS Results
ANA (+)	1	NR	NR
ASO (+)	2	NR	NR
ASO (+)	7	R	R
Bilirubin $ 20 mg/dl	20	NR	NR
Bilirubin $ 20 mg/dl	15	R	R
CRP (+)	2	NR	NR
Hemoglobin $ 10 mg/dl	21	NR	NR
Hemoglobin $ 10mg/dl	15	R	R
Infectious Mononucleosis (+)	3	NR	NR
Multiparous Women *	1	NR	NR
Post HBV Vaccination **	2	NR	NR
RF (+)	15	NR	NR
Rubella (+) **	14	NR	NR
Rubella (+) **	16	R	R
SLE (+)	2	NR	NR
Triglycerides $ 1000 mg/dl	21	NR	NR
Triglycerides $ 1000 mg/dl	15	R	R
Chlamydia	10	R	R
Herpes Simplex Virus	10	R	R
Lyme's Disease	12	NR	NR

* One specimen from a multiparous woman was Quantity Not Sufficient ** One specimen was both Post HBV Vaccination and Rubella (+)

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Random blood donor specimens (2293) and specimens of known reactivity were tested using the **ASI TPHA Test** reagents and the Olympus PK™ TP reagents on the Olympus PK7200™ instrument at three clinical sites. Donors who initially tested reactive or indeterminate on the Olympus PK7200™ with plasma samples were repeated using the same reagent again with the serum specimen, except for the known specimens. Specimens repeatedly testing reactive or indeterminate with either reagents and all known specimens were confirmed with MHATP and FTA-ABS tests. (See Table 12) The comparison of the two methods was done using a 95% confidence interval. That interval is 0.992 - 0.998

Table 12 **TEST SPECIFICITY**

ASI TPHA Test	Olympus PK7200™		FTA-ABS and MHATP Testing	
	R	NR	R	NR
Reactive (R)	341	0	341	0
Non-reactive (NR)	2	2305	0	2307
% Concordance	2646/2648 = 99.9%		2648/2648 = 100%	
Relative Sensitivity	341/343 = 99.4%		341/341 = 100%	
Relative Specificity	2305/2305 = 100%		2648/2648 = 100%	

24 REFERENCES

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