

RPR CARD TEST FOR SYPHILIS

For *in vitro* diagnostic use

<u>Catalog Number</u>	<u>Kit Size</u>
900025	25 Tests
900100	100 Tests
900500	500 Tests
9005000	5000 Tests
90010000	10000 Tests

CPT Code: 86592

INTENDED USE

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 as an aid in diagnosing syphilis and monitoring treatment effectiveness. The ASI RPR Card Test for Syphilis is for professional use only.

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 antigen¹, and anti-nontreponemal antibodies (reagin) that can be detected by RPR antigen².

PRINCIPLE OF THE PROCEDURE

The **ASI RPR Card Test** is an 8-minute macroscopic nontreponemal flocculation test to be used for the detection of reagin. 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.

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.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.

1. **ASI 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 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.
6. Negative results obtained for syphilis within three months of a high-risk event should be repeated at three months to confirm the initial negative result.

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. ASI RPR test cards are plastic coated and specifically designed to be used with the RPR antigen. In handling, take care not to fingerprint the card areas, as this may result in an oily deposit and improper test result. When spreading specimen within the confines of the circle area, avoid scratching the card with the stirrer pipets. If the specimen does not spread in the test area or spreads outside the test area, use another test circle.
3. The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. **Do not wipe the needle dry.** Place the needle back into the plastic sleeve. Do not remove bottle tip when washing the needle assembly. Let the assembly air dry. Before next use, make sure that no large water droplets remain in the dropping bottle by shaking the bottle and squeezing it.
4. The needle should deliver 60 ± 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy, check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 ± 1 drops are obtained in 0.5 ml.

5. Do not use past the expiration date indicated on the kit.
6. Do not interchange components from this kit with those of a different manufacturer. Discard the dispensing needle and dropping bottle when the carbon antigen is exhausted.

STORAGE INSTRUCTIONS

Store all reagents at 2–8°C in an upright position when not in use. Do not freeze reagents. Pipets and cards do not require refrigeration. Carbon Antigen may be stored for up to one month in the dropping bottle at 2–8°C; in this case, the needle must be cleaned at the end of each shift, using a syringe or pipet.

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. Specimens for visual reading
Use heated or unheated serum samples, and plasma specimens containing EDTA^{3,4}, CPD, CPDA-1, heparin or sodium cit- rate⁵ as anticoagulants. Plasma specimens should be from tubes or blood units which have been collected with adequate volume to provide the appropriate proportions of specimen to anticoagulant.
2. Samples should be free from bacterial contamination, gross hemolysis, or lipemia. A specimen is too hemolyzed for test- ing when printed matter cannot be read through it ².
3. Serum samples should be tested within five (5) days of collection. Optimum storage temperature for samples is 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 testing².
4. If needed, studies have shown that serum samples left on the clot for up to five (5) days at 45° C can be used. If the sample is hemolyzed, see item 3 above ⁵.
5. 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.
6. If necessary before testing, centrifuge the specimens at a force sufficient to sediment cellular components.
7. 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.
8. This test should not be used for testing spinal fluids.

PERFORMANCE OF THE TEST

Materials Provided:

	25 Tests	100 Tests	500 Tests*	5000 Tests*	10000 Tests*
RPR CARBON ANTIGEN	0.5 ml	2.0 ml	9.0 ml	10 x 9.0 ml	20 x 9.0 ml
REACTIVE CONTROL	0.5 ml	1.0 ml	2.0 ml	5 x 2.0 ml	5.0 ml
WEAK REACTIVE CONTROL	0.5 ml	1.0 ml	2.0 ml	5 x 2.0 ml	5.0 ml
NONREACTIVE CONTROL	0.5 ml	1.0 ml	2.0 ml	5 x 2.0 ml	5.0 ml
3 ml Dropping bottle	1	1	1	10	10
20-ga Dispensing needle (60 drops/ml)	1	1	1	10	10
RPR test card (10-well)	3	10	50	500	n/a
RPR test card (15-well)	n/a	n/a	35	350	675
RPR test card (30-well)	n/a	n/a	n/a	175	350
0.05 ml Disposable Stirrer Pipets	25	100	500	5000	10000

*Also available without controls

Additional Material Required

- Volumetric pipet to deliver 0.05 ml
- Saline (0.9% NaCl Solution)
- Serum nonreactive to syphilis, in 0.9% saline, for diluting specimens reactive at the 1:16 dilution in the semiquantitative procedure
- Mechanical rotator set at 100 ± 5 rpm and circumscribing ¾ inch diameter, with humidity cover
- Timing device, minute and second capability
- Disposable syringe, 1 or 3 ml, accuracy of ± 5%

PREPARATION FOR THE ASSAY

1. Allow all reagents and samples to warm to room temperature (20–30°C) before use. Remove reagents from foam holders. Do not heat reagents in a water bath.
2. All reagents are ready to use as supplied. Gently mix the reagents before use; avoid foaming.
3. Vigorously agitate the CARBON ANTIGEN for 20–30 seconds before each use in order to ensure homogeneity.

ASSAY PROTOCOL - QUALITATIVE

1. Using a stirrer pipet, dispense one free-falling drop (0.05 ml) of each serum or plasma sample onto a separate circle on the test card. Use a fresh stirrer pipet for each sample. When using the stirrer pipet, keep it in a vertical position to ensure accurate delivery. Repeat by adding one free-falling drop of REACTIVE, WEAK REACTIVE or NONREACTIVE CONTROL from the dropper vials supplied. Note the location of each sample by using the numbers located below and to the left of each circle.
2. Using the flat end of the stirrer pipet, spread the sample over the entire area of the test circle. Do not scratch the surface of the test area.

3. Attach the needle to the dropping bottle. Mix the CARBON ANTIGEN suspension well. Squeeze the dropping bottle and draw a sufficient volume of the antigen suspension into the bottle. Dispense several drops into the dropping bottle cap to make sure the needle passage is clear.
4. Prior to dispensing carbon antigen, agitate the dropping bottle for a few seconds to ensure reagent homogeneity. Dispense one free-falling drop of the antigen suspension onto each sample while holding the bottle in a vertical position. DO NOT RESTIR the sample and the antigen. Aspirate any antigen from the bottle cap.
5. Place the card on an automatic rotator and cover to maintain humidity. Rotate at 100 ± 5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds). Following rotation, a brief hand rotation and tilting of the card (at least 3–4 times) should be performed to aid in differentiating nonreactive from minimally reactive results.
6. Immediately read results macroscopically in the “wet” state under a high intensity light source.
7. Remove and wash the needle at the end of each shift.

ASSAY PROTOCOL - SEMIQUANTITATIVE

1. Using a stirrer pipet (or other accurate volumetric pipet capable of delivering 0.05 ml), dispense one free-falling drop of saline onto circles to be numbered 2 to 5. DO NOT SPREAD.
2. Using the stirrer pipet (or other accurate volumetric pipet capable of delivering 0.05 ml), dispense one free-falling drop of serum or plasma sample onto circle 1 on the test card. DO NOT SPREAD.
3. Using an accurate volumetric pipet, dispense 0.05 ml of the test sample onto circle 2. Insert the tip of the pipet into the resulting mixture and mix by carefully drawing the mixture up and down the pipet 5 or 6 times. Avoid any bubble formation.
4. Transfer 0.05 ml of the mixture in circle 2 to circle 3 and mix. Repeat this serial dilution procedure to circle 4 and then to circle 5; discard 0.05 ml from this last circle. Circles 1 through 5 now represent a dilution series as follows:

CIRCLE	1	2	3	4	5
DILUTION	1:1	1:2	1:4	1:8	1:16

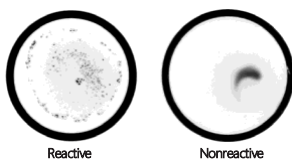
5. Using the flat end of the stirrer pipet, spread the diluted samples over the entire areas of the test circles, starting at circle 5 (highest dilution). Repeat the spreading procedure in circles 4 through 1.
6. Attach the needle to the dropping bottle. Mix the CARBON ANTIGEN suspension well. Squeeze the dropping bottle and draw a sufficient volume of the antigen suspension into the bottle. Dispense several drops into the dropping bottle cap to make sure the needle passage is clear.
7. Prior to dispensing carbon antigen, agitate the dropping bottle for a few seconds to ensure reagent homogeneity. Dispense one free-falling drop of the antigen suspension onto each sample while holding the bottle in a vertical position. DO NOT RESTIR the sample and the antigen. Aspirate any antigen from the bottle cap.
8. Place the card onto the automatic rotator and cover to maintain humidity. Rotate at 100 ± 5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds). Following rotation, a brief hand rotation and tilting of the card (3–4 times) should be performed to aid in differentiating nonreactive from minimally reactive results.
9. Immediately read results macroscopically in the “wet” state under a high intensity light source.
10. Remove and wash the needle at the end of each shift.

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.

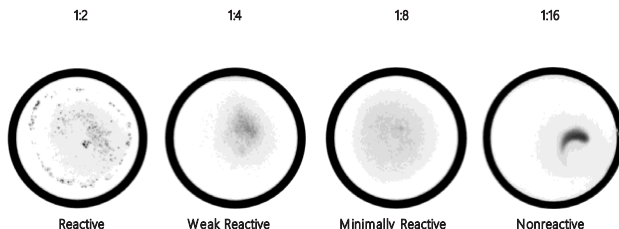
VISUAL INTERPRETATION OF RESULTS – QUALITATIVE

1. A reactive result is indicated by the presence of aggregates in the center or periphery of the test circle, ranging from slight to marked and intense. A nonreactive result will give a smooth gray appearance within the test circle or a button of nonaggregated carbon particles in the center of the circle, showing none of the clumping characteristics of a reactive result.
2. Results for the ASI RPR Card Test should be reported only as reactive or nonreactive, regardless of the degree of reactivity. Minimal to moderate reactivity should always be reported as reactive.
3. Slightly granular or “rough” reactions should be repeated using an alternate procedure. For donor screening, these should be reported as “indeterminate” pending further evaluation. See “Limitations of the Procedure” section.
4. If necessary, confirm reactive results by retesting the sample using the semiquantitative procedure.
5. It is not necessary to perform the quantitative procedure on reactive donor samples.



VISUAL INTERPRETATION OF RESULTS - SEMIQUANTITATIVE

1. The highest dilution in which visible aggregation occurs is considered the endpoint titer.



SAMPLES WITH TITERS GREATER THAN 1:16

1. Prepare a 1:50 dilution of nonreactive serum in saline. This is to be used for making 1:32 and higher dilutions of samples to be titrated. Dispense 0.05 ml of this solution onto circles labeled 2 through 5. DO NOT SPREAD
2. Prepare a 1:16 dilution of test sample by adding 0.1 ml of serum to 1.5 ml of saline. Mix thoroughly. Dispense 0.05 ml of this diluted sample onto circles 1 and 2. DO NOT SPREAD.
3. Mix the solution on circle 2 by drawing the solution up and down 5 or 6 times into the tip of a volumetric pipet. Avoid any bubble formation.
4. Transfer 0.05 ml of the mixture to circle 3 and mix as above. Continue the serial dilution through circle 5 and discard 0.05 ml from this last circle after mixing. Circles 1 through 5 represent a dilution series as follows:

CIRCLE	1	2	3	4	5
DILUTION	1:16	1:32	1:64	1:128	1:256

5. Proceed with the test as described in steps 13.5 through 13.9 under the "Semi-quantitative Assay Protocol".
6. Continue with additional dilutions as required until an endpoint titer is reached.

LIMITATIONS OF THE PROCEDURE

1. Prozone reactions occur in patients with secondary syphilis⁶. False negative nontreponemal test results, arising from prozone, are also seen in incubating primary and in late syphilis². 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.
2. 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.
3. Pinta, yaws, bejel and other treponemal diseases produce positive reactions in this test²
4. 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 it².
5. Reaction times longer than specified may cause false positive results due to a drying effect.
6. Reactive RPR test samples should be substantiated using a confirmatory test as recommended in the *Manual of Tests for Syphilis*²⁷.
7. Temperature of the reagents and samples is crucial to test outcome; it should be between 20-30°C.
8. In accord with all diagnostic methods, 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

1. In order to validate the specificity of the ASI RPR Card Test for Syphilis, testing was done using 5014 serum samples. All samples were clinical samples, none were contrived. Samples were characterized by the facilities that they were obtained from by RPR testing and then confirmed at Arlington Scientific prior to the study

Sensitivity:

5014 samples

Results of Testing			
Expected Results			
	Reactive	Nonreactive	
	Reactive	2117	63
	Nonreactive	50	2784

Sensitivity = 97.1%

Specificity:

5014 samples

Results of Testing			
Expected Results			
	Reactive	Nonreactive	
	Reactive	2117	63
	Nonreactive	50	2784

Specificity = 96.9%

Frozen Specimen Stability:

A total of 60 serum samples were split into two aliquots, one 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 specimens were allowed to come to room temperature before testing

The results of the testing are shown below:

Sample	Result	Result
	2-8°C	Frozen
1 - Nonreactive	NR	NR
2 - Nonreactive	NR	NR
3 - Nonreactive	NR	NR
4 - Nonreactive	NR	NR
5 - Nonreactive	NR	NR
6 - Nonreactive	NR	NR
7 - Nonreactive	NR	NR
8 - Nonreactive	NR	NR
9 - Nonreactive	NR	NR
10 - Nonreactive	NR	NR
11 - Nonreactive	NR	NR
12 - Nonreactive	NR	NR

13 - Nonreactive	NR	NR
14 - Nonreactive	NR	NR
15 - Nonreactive	NR	NR
16 - Nonreactive	NR	NR
17 - Nonreactive	NR	NR
18 - Nonreactive	NR	NR
19 - Nonreactive	NR	NR
20 - Nonreactive	NR	NR
21 – 1:1	R	R
22 – 1:1	R	R
23 – 1:1	R	R
24 – 1:1	R	R
25 – 1:1	R	R
26 – 1:1	R	R
27 – 1:1	R	R
28 – 1:1	R	R
29 – 1:1	R	R
30 – 1:1	R	R
31 – 1:1	R	R
32 – 1:1	R	R
33 – 1:1	R	R
34 – 1:1	R	R
35 – 1:1	R	R
36 – 1:1	R	R
37 – 1:1	R	R
38 – 1:1	R	R
39 – 1:1	R	R
40 – 1:1	R	R
41 – 1:2	R	R
42 – 1:2	R	R
43 – 1:2	R	R
44 – 1:2	R	R
45 – 1:2	R	R
46 – 1:4	R	R
47 – 1:4	R	R
48 – 1:4	R	R
49 – 1:4	R	R

50 – 1:4	R	R
51 – 1:8	R	R
52 – 1:8	R	R
53 – 1:8	R	R
54 – 1:16	R	R
55 – 1:16	R	R
56 – 1:32	R	R
57 – 1:32	R	R
58 – 1:64	R	R
59 – 1:64	R	R
60 – 1:128	R	R

Samples are stable up to one (1) month frozen.

Cross-Reactivity and Interference:

A study was conducted to evaluate potential interference or cross reactivity from different disease conditions.

The results of the testing are shown below:

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

The positive infectious mono samples were heterophil positive. EBV testing was not conducted.

The study showed no interference.

Analytical Claims:

Testing was performed using positive samples representing various stages of syphilis infection, including primary, secondary, and latent stages. Samples were numbered, noting each sample's gender, age, and race.

The results of the testing are contained in tables below:

Table 1 - Primary

Sample	Gender	Age	Race	Result
Primary Treated				
1	Female	18	Hispanic	R
2	Female	31	Caucasian	R
3	Female	33	Hispanic	R
4	Female	31	Hispanic	R
5	Female	21	Caucasian	R
6	Female	28	Hispanic	R
7	Female	32	Caucasian	R
8	Female	30	Hispanic	R
9	Female	22	Caucasian	R
10	Female	31	Hispanic	R
11	Female	35	Caucasian	R
12	Female	27	Caucasian	R
13	Female	34	Caucasian	R
14	Female	24	Caucasian	R
15	Female	25	Caucasian	R
16	Female	34	Caucasian	R
17	Female	33	Caucasian	R
18	Female	29	Caucasian	R
19	Female	35	Caucasian	R
20	Female	29	Caucasian	R
21	Female	34	Caucasian	R
22	Female	35	Hispanic	R
23	Female	35	Caucasian	R
24	Female	34	Caucasian	R
25	Female	23	Caucasian	R
Primary Untreated				
1	Female	18	Hispanic	R
2	Female	34	Caucasian	R
3	Female	20	Caucasian	R
4	Female	17	Caucasian	R
5	Female	32	Hispanic	R
6	Female	23	Hispanic	R
7	Female	21	Caucasian	R
8	Female	33	Caucasian	R
9	Female	21	Caucasian	R
10	Female	24	Hispanic	R
11	Female	25	Asian	R
12	Female	28	Caucasian	R
13	Female	34	Hispanic	R
14	Female	22	Caucasian	R
15	Female	23	Hispanic	R
16	Female	31	Caucasian	R
17	Female	30	Hispanic	R
18	Female	34	Caucasian	R

Table - Secondary

Sample	Gender	Age	Race	Result
Secondary Treated				
1	Male	24	Hispanic	R
2	Male	38	Hispanic	R
3	Male	29	Hispanic	R
4	Male	47	Hispanic	R
5	Male	51	Hispanic	R
6	Male	49	Hispanic	R
7	Male	34	Hispanic	R
8	Male	41	Hispanic	R
9	Male	44	Hispanic	R
10	Male	26	Hispanic	R
11	Male	58	Hispanic	R
12	Male	25	Hispanic	R
13	Male	39	Hispanic	R
14	Male	50	Hispanic	R
15	Male	42	Hispanic	R
16	Male	31	Hispanic	R
17	Male	58	Hispanic	R
18	Male	38	Hispanic	R
19	Male	46	Hispanic	R
20	Male	29	Hispanic	R
21	Male	45	Hispanic	R
22	Male	24	Hispanic	R
23	Male	51	Hispanic	R
24	Male	40	Hispanic	R
25	Male	54	Hispanic	R
Secondary Untreated				
1	Female	24	Caucasian	R
2	Female	20	Caucasian	R
3	Female	30	Caucasian	R
4	Female	33	Hispanic	R
5	Female	21	Hispanic	R
6	Female	26	Hispanic	R
7	Female	34	Caucasian	R
8	Female	18	Caucasian	R
9	Female	20	Caucasian	R
10	Female	17	Caucasian	R
11	Female	28	Hispanic	R
12	Female	23	Hispanic	R
13	Female	33	Caucasian	R
14	Female	21	Caucasian	R
15	Female	19	Caucasian	R
16	Female	21	Hispanic	R
17	Female	22	Caucasian	R
18	Female	24	Caucasian	R
19	Female	25	Hispanic	R
20	Female	33	Hispanic	R
21	Female	21	Hispanic	R
22	Female	31	Caucasian	R
23	Female	23	Hispanic	R
24	Female	20	Hispanic	R
25	Female	26	Caucasian	R

Table - Latent

Sample	Gender	Age	Race	Result
Latent Treated				
1	Female	28	African/American	R
2	Female	36	Hispanic	R
3	Female	56	African/American	R
4	Female	49	African/American	R
5	Male	55	African/American	R
6	Female	58	Hispanic	R
7	Female	25	African/American	R
8	Male	61	African/American	R
9	Male	46	African/American	R
10	Male	58	African/American	R
11	Female	44	African/American	R
12	Male	71	Hispanic	R
13	Female	52	Hispanic	R
14	Female	55	African/American	R
15	Female	55	African/American	R
16	Male	72	African/American	R
17	Male	50	African/American	R
18	Female	32	African/American	R
19	Female	60	African/American	R
20	Female	Unk	African/American	R
21	Female	42	Hispanic	R
22	Female	66	African/American	R
23	Male	50	African/American	R
24	Male	37	African/American	R
25	Male	51	African/American	R
Latent Untreated				
1	Female	31	Hispanic	R
2	Female	30	Hispanic	R
3	Female	26	Caucasian	R
4	Female	31	Hispanic	R
5	Female	35	Caucasian	R
6	Female	30	Hispanic	R
7	Female	31	Hispanic	R
8	Female	28	Caucasian	R
9	Female	34	Caucasian	R
10	Female	35	Hispanic	R
11	Female	27	Caucasian	R
12	Female	20	Caucasian	R
13	Female	34	Caucasian	R
14	Female	31	Caucasian	R
15	Female	29	Caucasian	R
16	Female	33	Caucasian	R
17	Female	25	Hispanic	R
18	Female	35	Caucasian	R
19	Female	26	Hispanic	R
20	Female	24	Caucasian	R
21	Female	19	Hispanic	R
22	Female	24	Hispanic	R
23	Female	24	Hispanic	R
24	Female	19	Caucasian	R
25	Female	28	Caucasian	R

The data shows all testing results were as expected.

Additional testing was conducted using specimens from pregnant women. 250 nonreactive syphilis samples and 30 reactive syphilis samples were tested. All results were as expected, no interference from the type of specimen noted. Samples consisted of a wide range of age and all three trimesters of pregnancy⁵.

REFERENCES

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3. Larsen SA, Pettit DE, Perryman MW, Hambie EA, Mullally R, Whittington W. 1983. *J Clin Microbiol*, **17**:341-345.
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TECHNICAL INFORMATION: (801) 489-8911 or (800) 654-0146



Arlington Scientific, Inc.

1840 N Technology Drive, Springville, UT 84663
USA 1-800-654-0146, 1-801-489-8911, Fax 801-489-5552
info@arlingtonscientific.com
www.arlingtonscientific.com



MedEnvoy Global B.V.

Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
The Netherlands

