510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K111356

B. Purpose for Submission:

To determine substantial equivalence for the ASiManager-AT

C. Manufacturer and Instrument Name:

Arlington Scientific Inc. ASiManager-AT

D. Type of Test or Tests Performed:

Digital interpretation of visual results obtained with ASI RPR card test for syphilis

E. System Descriptions:

1. Device Description:

The ASiManager-AT is an integrated digital particle analyzer designed to objectively interpret certain slide agglutination tests manufactured by Arlington Scientific, Inc. (ASI). Qualitative and semi quantitative tests are performed by laboratory professionals who use the ASiManager-AT to provide standardized test interpretation using criteria that define reactive and nonreactive agglutination reactions. The **ASiManager-AT** also delivers an initial predictive titer analysis for the ASI RPR Card Test for Syphilis.

The ASiManager-AT consists of :

- A Computer/Monitor
- Imaging Unit and Drawers
- Wireless Keyboard and Mouse
- Monitor Cables and Power Adaptor
- ASiManager-AT Calibration Check Cards

2. Principles of Operation:

The ASiManager-AT employs a CCD (charge-coupled device) 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 instrument

compares the high resolution digital picture of each well to built in preset parameters and reports the results as reactive or non reactive. A numerical index of ≤ 800 is recorded as non reactive and a numerical index of ≥ 801 is recorded as reactive. The ASiManager-AT further provides tools that enable the creation, storage, retrieval and transmittal of the test results.

3. Modes of Operation:

   The ASiManager-AT is an instrument that has an integrated PC and preloaded software. The instrument uses a CCD camera at a precise focal point to capture the image of a test circle on ASI's particle agglutination test cards. The image results are passed to an integrated PC and software to provide an easy to use application for reviewing and distributing results.

4. Specimen Identification:

   The Asi RPR card test for syphilis is first performed correctly and results read prior to being analyzed by the ASiManager-AT.

5. Specimen Sampling and Handling:

   After performing the ASI RPR Card Test for syphilis tests, the RPR card is inserted into the device holder of the ASiManager-AT. The Multi Sample Measuring Mode in the instrument allows for examinations on the basis of sample ID numbers. The software automatically inserts the sample ID numbers into a worklist. Then the test is run and results can be viewed singly.

6. Calibration:

   ASiManager-AT Calibration Check Cards are provided with the system and may be used at user's convenience as an aid to ensure that the instrument is performing as expected. ASI recommends that the ASiManager-AT Calibration Check Cards be used after the initial set-up and periodically as needed.

7. Quality Control:

   Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and the 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, the user should discontinue use and contact ASI Technical Support.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes ___X____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.2400 – Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use

2. Classification:

   Class I

3 Product code:

   JQT

4. Panel:

   Clinical Chemistry

G. Intended Use:

1. Indication(s) for Use:

   The ASiManger-AT is intended to be used as an integrated digital particle analyzer to objectively interpret the ASI RPR Card Test for syphilis. The ASiManger-AT is designed to provide standardized test interpretation, an initial predictive titer analysis, and provides for storage, retrieval and transmittal of the test results. It is intended to be acquired, possessed and used only by healthcare professionals. For *in vitro* Diagnostic Use Only, not intended for screening blood and tissue donors.

2. Special Conditions for Use Statement:

   It is intended to be acquired, possessed and used only by healthcare professionals.

H. Substantial Equivalence Information:

1. Predicate Device Name and 510(k) number:

   ASI RPR Card Test for syphilis – K851504

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	To interpret results of the ASI RPR Card Test for syphilis	Same

Differences		
Item	Device	Predicate
Result Interpretation	Interprets slide agglutination tests objectively with digital particle analyzer	Interprets slide agglutination tests visually
Function	Create, store, retrieve and transmit test results	N/A

I. Special Control/Guidance Document Referenced:

N/A

J. Performance Characteristics:

1. Analytical Performance:

   a. Accuracy

   Analytical specificity and accuracy over a wide range of known titers, was evaluated using samples of known reactivity. The ASiManager-AT identified the 1802 reactive samples and the 1617 nonreactive samples correctly. The ASiManager-AT also identified the 700 of 708 titer samples within ±1 dilution titer, with titers ranging from 1:1 to 1:1024 correctly.

   b. Precision/Reproducibility:
   Repeatability is defined as the variation in measurements taken by a single instrument on the same item and under the same conditions.
   A total of 10 samples using the ASI RPR Card Test for Syphilis and the ASiManager-AT were evaluated for reactivity, predictive titer, and end-point titer.

The testing requirements were as follows:

1. All qualitative and semiquantitative testing was conducted according to the procedure in the package insert.
2. Each qualitative sample was tested 100 times.
3. Immediately after the testing of each card was completed the results were visually interpreted.
4. The end-point titer was determined for all reactive samples 10 times.
5. After visual interpretation the test card was placed in the ASiManager-AT for analysis.
6. The predictive titer was determined by the ASiManager-AT using only the undiluted sample.
7. All reactive samples had their end-point titers determined by the ASiManager-AT.

A total of 10 samples were evaluated to determine repeatability of reactivity and end-point titer. Of the 10 samples, 5 were reactive and 5 were nonreactive visually. The reactive samples had titers of 1, 2, 4, 8 and 32. Each of the 10 samples was repeated 100+ times to evaluate the reactivity and predictive titer using the ASiManager-AT. Refer to Table 18.8 below

Table 18.8

Sample	Predictive Titer		% Concordance
1	1:1	100/100	100%
2	1:2	83/100	83%
3	1:4	102/110	93%
4	1:8	90/100	90%
5	1:32	74/110	67%
6	NR	100/100	100%
7	NR	100/100	100%
8	NR	100/100	100%
9	NR	100/100	100%
10	NR	100/100	100%

Since the predictive titer is estimated from only the undiluted specimen, it is acceptable that the result range above 1:1 is within ±1 dilution. The results within ±1 dilution are in Table 18.9.

Table 18.9

Sample	Predictive Titer within ±1 titer		% Concordance
1	1:1	100/100	100%
2	1:2	100/100	100%
3	1:4	110/110	100%
4	1:8	100/100	100%
5	1:32	98/110	89%
6	NR	100/100	100%
7	NR	100/100	100%
8	NR	100/100	100%
9	NR	100/100	100%
10	NR	100/100	100%

The end-point titers of the 5 reactive samples were determined by the ASiManager-AT and were repeated 10 times. The results are contained in Table 18.10

Table 18.10

Sample	End-point Titer		% Concordance
1	1:1	10/10	100%
2	1:2	10/10	100%
3	1:4	10/10	100%
4	1:8	10/10	100%
5	1:32	10/10	100%

The data above show that the ASiManager-AT gives an objective and standardized interpretation of the test results with a high degree of repeatability. There is some variability in the predictive titer due to its interpretation by the undiluted specimen only. Giving the allowance of ±1 dilution titer the repeatability was greatly improved.
The actual end-point titer has a high degree of repeatability.
Additional repeatability testing was done in-house. The testing consisted of: three samples, a RPR nonreactive sample, an RPR reactive 1:1 titered sample (minimum cutoff) and a RPR reactive 1:4 titered sample (moderate reaction).Each sample was tested each morning for twelve days by an operator with experience in performing the ASI RPR Card Test for Syphilis and operating the ASiManager-AT. Each sample was tested each afternoon for twelve days by a different operator with experience in performing the ASI RPR Card Test for Syphilis and operating the ASiManager-AT. Each of the three samples was run in triplicate on the morning and afternoon runs. Testing was performed on the same ASiManager-AT.
The results of the testing are contained in Table 18-11 below

Table 18-11

Sample	Expected	Results												% Agreement Positive
		ASiManager-AT #3												
	Date	7/28	7/29	8/1	8/2	8/3	8/4	8/5	8/8	8/9	8/10	8/11	8/12	
Operator 1														
1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	100%
	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
2	1:1	1:1	1:1	1:1	1:1	1:1	NR	1:1	1:1	1:1	1:1	1:1	1:1	97.2%
	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	
	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	
3	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	100%
	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	
	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	
Operator 2														
1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	100%
	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	
2	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	94.4%
	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	NR	1:1	1:1	
	1:1	1:1	1:1	1:1	1:1	1:1	NR	1:1	1:1	1:1	1:1	1:1	1:1	
3	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	100%
	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	
	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	

The data shows a 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 12 samples using the ASI RPR Card Test for Syphilis and the ASiManager-AT were evaluated for reactivity and predictive titer. The testing requirements were as follows:

All qualitative and semiquantitative testing was conducted using the procedure in the package insert.
Each sample was tested 10 times.
After the testing was completed the results were visually interpreted.
After visual interpretation the test card was placed in the ASiManager-AT for analysis.
The predictive titer was determined by the ASiManager-AT using only the undiluted sample.
After the analysis in the first ASiManager-AT, the same test card was placed into another ASiManager-AT and then repeated through 4 instruments.
A total of 12 samples were evaluated to determine reproducibility of reactivity and end-point titer among the four instruments. Of the 12 samples, 9 were reactive and 3 were

nonreactive visually. The reactive samples had titers ranging from 1:1 to 1:16. Each of the 12 samples was analyzed once on each of the four instruments to evaluate the reactivity and predictive titer. The data are shown in the Table 18-12 below.

Table 18-12

Sample	Expected	Results within ±1 Titer				% Concordance
		ASiM-2	ASiM-3	ASiM-4	ASiM-5	
1	NR	10/10	10/10	10/10	10/10	100%
2	NR	10/10	10/10	10/10	10/10	100%
3	NR	10/10	10/10	9/10	10/10	97.5%
4	1:1	10/10	8/10	9/10	9/10	90%
5	1:1	10/10	10/10	10/10	10/10	100%
6	1:2	10/10	10/10	10/10	10/10	100%
7	1:4	10/10	9/10	9/10	9/10	92.5%
8	1:4	10/10	10/10	10/10	10/10	100%
9	1:4	10/10	10/10	10/10	9/10	97.5%
10	1:4	10/10	10/10	10/10	10/10	100%
11	1:8	10/10	10/10	10/10	10/10	100%
12	1:16	10/10	10/10	10/10	10/10	100%
Totals		120/120	117/120	117/120	117/120	98.1%

The data above show that the ASiManager-AT gives an objective and standardized interpretation of the test results with good reproducibility. There was some variability in the predictive titer due to it being interpreted on the undiluted specimen only. However with the allowance of ±1 dilution titer, the reproducibility is greatly improved.
Additional reproducibility testing was conducted at 3 outside sites and in-house.
Testing was conducted on 10 samples, consisting of three RPR nonreactive samples, four RPR reactive 1:1 titered samples (minimum cutoff) and three RPR reactive 1:4 titered samples (moderate reaction).
Each sample was tested on two consecutive days by a different operator with experience in performing the ASI RPR Card Test for Syphilis and operating the ASiManager-AT.
Each of the three samples was run in triplicate.
The results of the testing are contained in Table 18-15:

Table 18-15

Sample	Expected	Results								% Agreement Positive
		Arlington Scientific		Qualtex		Mississippi Valley		Georgia Dept. Health		
		Day 1	Day 2	Day 1	Day 2	Day 1	Day 2	Day 1	Day 2	
1	NR	NR	NR	NR	NR	NR	NR	NR	NR	100%
2	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	100%
3	NR	NR	NR	NR	NR	NR	NR	NR	NR	100%
4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	100%
5	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	100%
6	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	1:4	100%
7	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	100%
8	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	100%
9	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	100%
10	NR	NR	NR	NR	NR	NR	NR	NR	NR	100%

The data shows a high degree of reproducibility.

c. Linearity:

N/A

d. Carryover:

N/A

e. Interfering Substances:

N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

The digital interpretation of the results by the ASiManager-AT instrument was compared to the visual interpretation of the results of samples tested at 3 sites with the ASI RPR Card Test for Syphilis. Results are as follows:

Combined Prospective Sample Testing - 375 samples

		ASiManager-AT Digital Results	
		Reactive	Nonreactive
Visual Results	Reactive	3	0
	Nonreactive	0	372

These results give a percent agreement positive of 100% with reactive samples and 100% with nonreactive samples.

Combined Retrospective Sample Testing - 3131 Samples

		ASiManager-AT Digital Results	
		Reactive	Nonreactive
Visual Results	Reactive	1799	58
	Nonreactive	29	1245

These results give a percent agreement positive of 98.4% with reactive samples and 95.5% with nonreactive samples.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.