Evaluation of the AIX1000 Automated Test System for Rapid Plasma Reagin (RPR) Syphilis Testing

Tamara R. Fox[1] and Patricia Slev[1, 2]

[1]ARUP Laboratories, Institute for Clinical and Experimental Pathology, Salt Lake City, UT, USA; [2]Department of Pathology, University of Utah, Salt Lake City, UT, USA

Objective

Rapid Plasma Reagin (RPR) is the classic non-treponemal serological screening assay used for identifying patients suspected of having Syphilis. [1-4] The manual agglutination method is subjective and time consuming, requiring trained laboratory personnel. The AIX1000 RPR Test System by Gold Standard Diagnostics (GSD, Davis, CA) is a fully automated method for performing RPR that reads results using an algorithm developed from over 100,000 images. Our objective was to determine the performance of the AIX1000 and its suitability as a replacement for the manual RPR method.

Methods

- One hundred patient sera submitted to ARUP Laboratories for RPR testing (manual method; ASi, Springville, UT) were analyzed.
- All samples were tested on both the ASi manual method and the GSD automated method, then compared.
- Antigen used for the agglutination testing on both assays is the same activated charcoal particle to which cardiolipin, lecithin, and cholesterol antigens are attached.
- ±2 titers were considered in agreement and all samples were titered to endpoint for both assays.

ASi interpretation

- Sera were considered Reactive based on visual identification of macro level agglutination. Sera were considered Non-Reactive if no agglutination was observed.

AIX1000 Interpretation

- Statistical Anlaysis of Grey-scale histogram is used to determine results. Titer is determined by the last well to be determined Reactive by the algorithm.
- Algorithm was trained on more than 100,000 images.

RPR Interpretation

ASi Manual Method

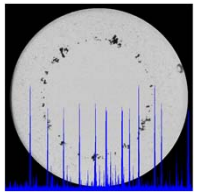
Strong Reactive

Reactive

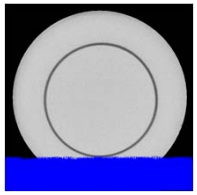
Weak Reactive

Non-Reactive

AIX1000 Automated Method



Reactive



Non-Reactive

Results

Semi-quantitative Agreement Between the ASi and the AIX1000

Excellent overall semi-quantitative agreement of 94% (positive agreement of 88%, negative agreement of 100%) when the manual ASi assay results were compared to the AIX1000 results. Excel software was used to analyze agreement between assays

100 samples		AIX1000	
		Reactive	Non-Reactive
ASi	Reactive	44	6
	Non-Reactive	0	50

	Results Within ± 2 Titers		
	ASi	AIX1000	Agreement
Positive	50	44	88%
Negative	50	50	100%
Overall	100	94	94%

Conclusions

The automated AIX1000 RPR test system showed excellent semi-quantitative agreement when compared to the ASi manual method and is an acceptable replacement for the ASi manual method. The AIX1000, while requiring a higher upfront cost, reduces the cost of labor as it does not require a Medical Laboratory Scientist's expertise. The AIX1000 has the added benefits of being fully automated making it less time consuming and delivering objective result interpretation, removing the variation of subjective interpretation.

Acknowledgements

We would like to thank Gold Standard Diagnostics for the use of the instrument and reagents; and the Microbial Immunology II Lab at ARUP Laboratories for testing during the validation. This study was funded by the ARUP Institute of Clinical and Experimental Pathology and the Department of Pathology, University of Utah School of Medicine, Salt Lake City, UT.

References

1. Peeling R.W., and Hook E.W. J. Pathol. 208(2): 224-234. 2006.
2. Larsen S., et. al. Washington: American Public Health Association, 1990. 9th ed.
3. Tomizawa T. and Kasamatsu S. J. Med. Sci. Biol. 19, 305-308, 1966.
4. Van der Sluis, JJ. Genitourin Med. 38, 413-419, 1992.

ARUP LABORATORIES

HEALTH UNIVERSITY OF UTAH