PUBLIC HEALTH LABORATORY DIRECTORS OF TEXAS

Arlington Scientific, Inc. (ASI)

Introduction to:

“Most important innovation to RPR Testing in the last 30 years”
Your Syphilis Authority

Expertise
- RPR
- VDRL
  CDC Licensed Synthetic Formula
- TPHA
- Syphilis Reference Panels
- Custom Kits and Controls

Industry Firsts
- Mercury Free
- EDTA, CPD or CPDA-1
- Liquid Controls
- Screwcap Lids
- Warp Resistant Cards
- Extended Dating
- ASiManager-AT™
  RPR Digital Analyzer
ASI RPR Card Test for Syphilis

- Superior readability
- Carbon antigen supplied in screw cap vials
  - no glass ampoule to break
- Three level liquid controls included
- Cards plastic coated on both sides
  - warp resistant
- Complete kit – everything needed to perform the test is included in the kit
- Long dating
  - up to 24 months
RPR Testing

**PROs**
- CDC recommendation
- Proven reliability
- Cost effective technology
- Easy-to-use
- Solution for all size laboratories

**CONs**
- Subjective interpretation
- No image storage or retrieval
- Eye fatigue
- Transcription errors
- Data management
Validation Report
For RPR
(ASI KIT)
ESOTERIC DEPARTMENT

Validation Performed By: Agnes Madolid
Validation Accepted By: Michael Mahoney, MD

Relative Sensitivity: 100%
Relative Specificity: 100%
LabCorp Evaluation of ASI RPR

- “More defined endpoint”
- “Clearer, easier to read”
- “All testing materials included”
- “Coated cards resist warping”
- “Thicker cards easier to handle”
- “More defined test card wells”
- “One part number, packaging superior”
- “Convenience - ready to use controls”
- “Superior readability”

LabCorp Esoteric Dept. Raritan, NJ
ASI Kit Validation
Combined CAP, AAB, and API Surveys
CDC recommends the traditional algorithm with reactive nontreponemal tests confirmed by treponemal testing.

*Discordant Results from Reverse Sequence Syphilis Screening --- Five Laboratories, United States, 2006—2010

MMWR February 11, 2011
www.cdc.gov/mmwr/preview/mmwrhtml/mm6005a1.htm
CDC Letter to Colleagues

Dr. Gail Bolan, Director, Division of STD Prevention

Recommends traditional screening algorithm using RPR or VDRL

Letter to physicians from CDC about MMWR February 2011 Report:
Syphilis Screening Algorithms

CDC Recommended Screening

- **RPR** (Nontreponemal)
  - **RPR +**
  - **TP-PA** or other trep. test
    - **TP-PA +** Syphilis (past or present)
    - **TP-PA -** Syphilis unlikely
  - **RPR -**

Reverse Sequence Screening

- **EIA or CIA** (Treponemal)
  - **EIA/CIA +**
  - **Quantitative RPR**
    - **RPR +** Syphilis (past or present)
    - **RPR -**
    - **TP-PA**
      - **TP-PA +** Syphilis (past or present)
      - **TP-PA -** Syphilis unlikely
  - **EIA/CIA -**
“Most important innovation to RPR testing in the last 30 years”
Solution: Digital Analysis

- Objective and standardized interpretation
- Retrievable image and results
- Easy-to-use
- Cost effective
- LIMS capable
- Increased reliability
- RPR predictive titers
- Barcode reader
Established 1985
27+ years medical device manufacturing
USA serology market leader
All products made in the USA
Syphilis authority
Award winning quality & service

Certifications
U.S. Reg#1641328
U.S. small business
Europe
China
System Check

- System Check Card ensures the instrument is performing as expected
Evaluation of a Digital Floculation Reader for the Rapid Plasma Reagin Test for the Serological Diagnosis of Syphilis

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Abstract: The study was conducted to evaluate the ASiManager-AT digital floculation reader. To determine the concordance between visual and digital readings of the rapid plasma reagin test for detection of antibodies in the serum of patients with syphilis. A qualitative and quantitative evaluation of plasma samples was performed. Sensitivity and specificity of 98.6% and 99.7%, respectively, were determined for visual and computer-assisted readers.

From the Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, GA; Arlington Scientific, Inc., Springville, UT; and Georgia Public Health Laboratory, Atlanta, GA. The authors thank the Georgia Department of Health Laboratories for supplying specimens for the study and Arlington Scientific for supplying the necessary diagnostic reagents for this study. Supported by the Centers for Disease Control and Prevention in the form of the National Immunization Program in the testing of the rapid plasma reagin test. The authors thank the Georgia Department of Health Laboratories for supplying specimens for the study and Arlington Scientific for supplying the necessary diagnostic reagents for this study. Supported by the Centers for Disease Control and Prevention in the form of the National Immunization Program in the testing of the rapid plasma reagin test.

A.D.R.C. was the project microbiologist, developed the floculation protocol, designed the test parameters and function of the floculation reader, performed the statistical analysis, and wrote the manuscript. All authors contributed to the study design and approved the final draft.

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One of the authors of the Laboratory Reference and Research branch (LRRB) of the Division of STD Prevention of the National Center for HIV/AIDS, STD and TB Prevention of the Centers for Disease Control and Prevention is a co-author of this paper. No other financial interests are disclosed in this manuscript. The authors of this manuscript are not affiliated with the Centers for Disease Control and Prevention.

The Centers for Disease Control and Prevention (CDC) recommends syphilis serologic testing with a non-reactive or non-concordant test, such as the rapid plasma reagin test (RPR), to identify persons with possible undiagnosed infections. The ASiManager-AT digital floculation reader provides a tool for retrieval of documentation and archival of records.

Methods:

The antigen is prepared from a Vero cell line, which is a continuous cell line derived from a variety of species, and is added to the test tube to initiate the reaction. The antigen will react with a variety of biological materials, including blood, urine, and cerebrospinal fluid. The test is a qualitative and quantitative test for the detection of antibodies against syphilis. The test is performed by adding the antigen to a test tube and incubating at room temperature for 30 minutes. The test is read visually, and a positive result is indicated by the presence of a precipitate.
ASiManager-AT Performance

Sensitivity - 98.1%
Specificity - 99.4%

INDEPENDENT TESTING AT 5 SITES

<table>
<thead>
<tr>
<th>Visual Results</th>
<th>Reactive</th>
<th>Nonreactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>2178</td>
<td>43</td>
</tr>
<tr>
<td>Nonreactive</td>
<td>20</td>
<td>3274</td>
</tr>
</tbody>
</table>
Available Tests

- RPR
- SLE MONO ASO
- RF
- CRP
- ASO
- Rubella
• World’s first digital RPR analyzer
• Objective and Standardized results
• Results and image management
  – Analyze
  – Document
  – Store
  – Retrieve
• CDC proven and FDA cleared
• RPR reliability, quality and cost effectiveness
• Removes RPR Subjectivity
ASI Offers Data Management Innovative and Intuitive Software

• Analyze – Archive – Retrieve Digital Data
• Objective interpretation removes subjectivity
• Reduced labor costs & Workflow increase
• Proprietary technology – Proprietary software
• State-of-the-art graphic user interface
• Create and print patient reports, actual test images and QC reports
• LIMS compatible with bi-directional interface
ASI - “Your Syphilis Authority” Creating The Future of Syphilis Testing

- Affordable – lowest cost per test .....  
  RPR Reagents are far less expensive than treponemal reagents
- Easy-to-use with minimal training
- Installation, validation, training, service and support provided

ASI..Devoted to The Future of Syphilis Testing

- ThunderBolt ASI Fully Automated Syphilis Analyzer (Pending FDA Clearance)
- National Institute of Health Product Development
- Dual Platform Nontreponemal / Treponemal Test
THANK YOU