



Florida Department of Health
Division of Disease Control and Health Protection
Bureau of Public Health Laboratories

2019 HIV Diagnostics Conference
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Performance of the Syphilis Reverse Algorithm Using the Abbott Architect Syphilis TP (ASTP) and its Role in a “Blended” Diagnostic Application in Florida’s Public Health Testing Population

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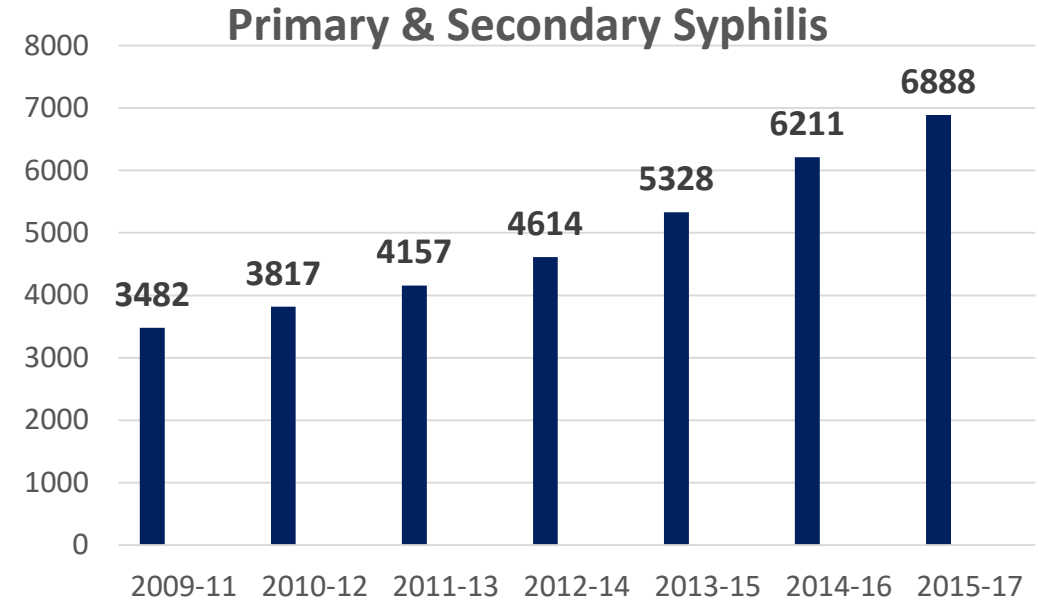
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Conflict of Interest statement: I do not have any financial relationship with commercial entities to disclose.

Primary and Secondary Syphilis in Florida

Infectious Syphilis Cases, Rate Per 100,000 Population, 3-Year Rolling				
Year	Count	Denom	Rate	MOV (+/-)
2015-17	6,888	60,684,582	11.4	0.3
2014-16	6,211	59,708,725	10.4	0.3
2013-15	5,328	58,792,029	9.1	0.2
2012-14	4,614	58,013,205	8.0	0.2
2011-13	4,157	57,375,076	7.2	0.2
2010-12	3,817	56,880,960	6.7	0.2
2009-11	3,482	56,473,866	6.2	0.2
2008-10	3,266	56,168,961	5.8	0.2
2007-09	2,997	55,849,639	5.4	0.2
2006-08	2,691	55,375,391	4.9	0.2



From 2009-11 to 2015-2017 there was a 97.8 % increase in the 3 year rolling average for Primary & Secondary Syphilis

In 2017 the rate for Primary and Secondary Syphilis was 11.6 cases per 100,000

Nationally the Rate was 9.5 cases/100,000

<http://www.flhealthcharts.com/charts/OtherIndicators/NonVitals/TDDDataViewer.aspx?cid=0144>



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3 Locations – Jacksonville, Miami and Tampa

Jacksonville Serology	2018 Total Tests
Syphilis (Traditional Algorithm) – RPR/EIA/TP-PA	61,646
Hepatitis A, Hepatitis B (Surface Antigen, Surface Antibody and Core), and Hepatitis C	67,478
HCV RNA NAAT (diagnostic and viral load)	2,957
Chlamydia trachomatis Amplified Testing	92,728
Neisseria gonorrhoea Amplified Testing	92,728
Rubella screen (qualitative only)	1,749
QuantiFeron QFT-TB Plus	1,694



OBJECTIVE

To compare the performance and sensitivity of the syphilis Reverse Algorithm with the Traditional Algorithm for detecting primary and secondary (P&S) infectious syphilis cases in the Florida public health population.



METHOD

- A retrospective study of individuals who self-referred at county public health clinics for syphilis testing.
- All specimens were processed through the Traditional Algorithm.
 - Primary screening performed with the Rapid Plasma Reagin (RPR) Card Test; all reactives were tested semi-quantitatively to yield a titer.
 - All initial reactive specimens were confirmed by the TrepSure EIA.
 - Any discordant RPR/EIA specimens were tested by the Treponema pallidum Particle Agglutination (TP-PA) assay.



METHOD (cont.)

All specimens were also processed through the Reverse Algorithm

- Primary screening performed with the Abbott ARCHITECT Syphilis TP CMIA (ASTP).
- All initial reactive specimens were confirmed by RPR.
- Any discordant ASTP/RPR specimens were tested by TP-PA.

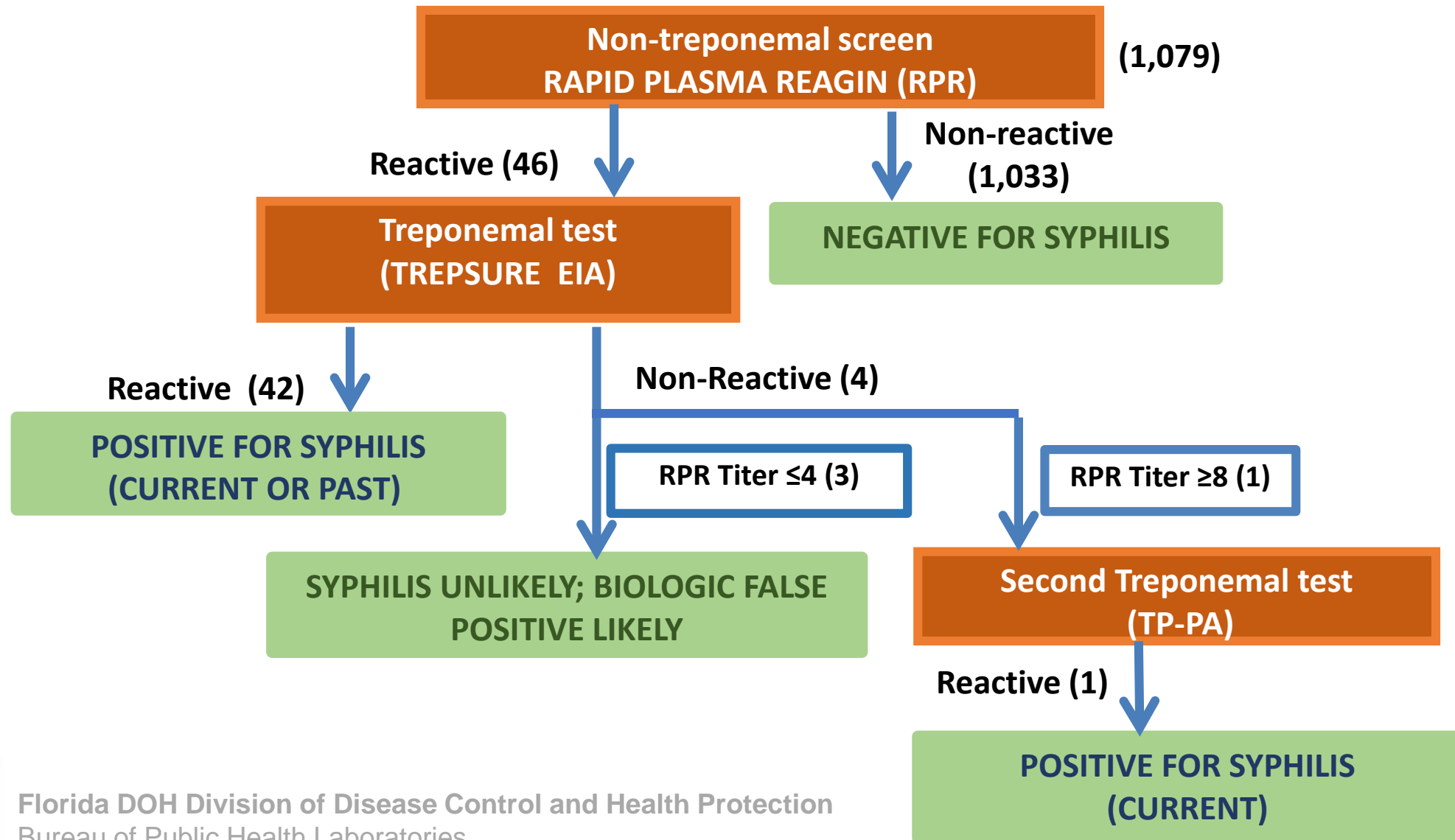


METHOD (cont.)

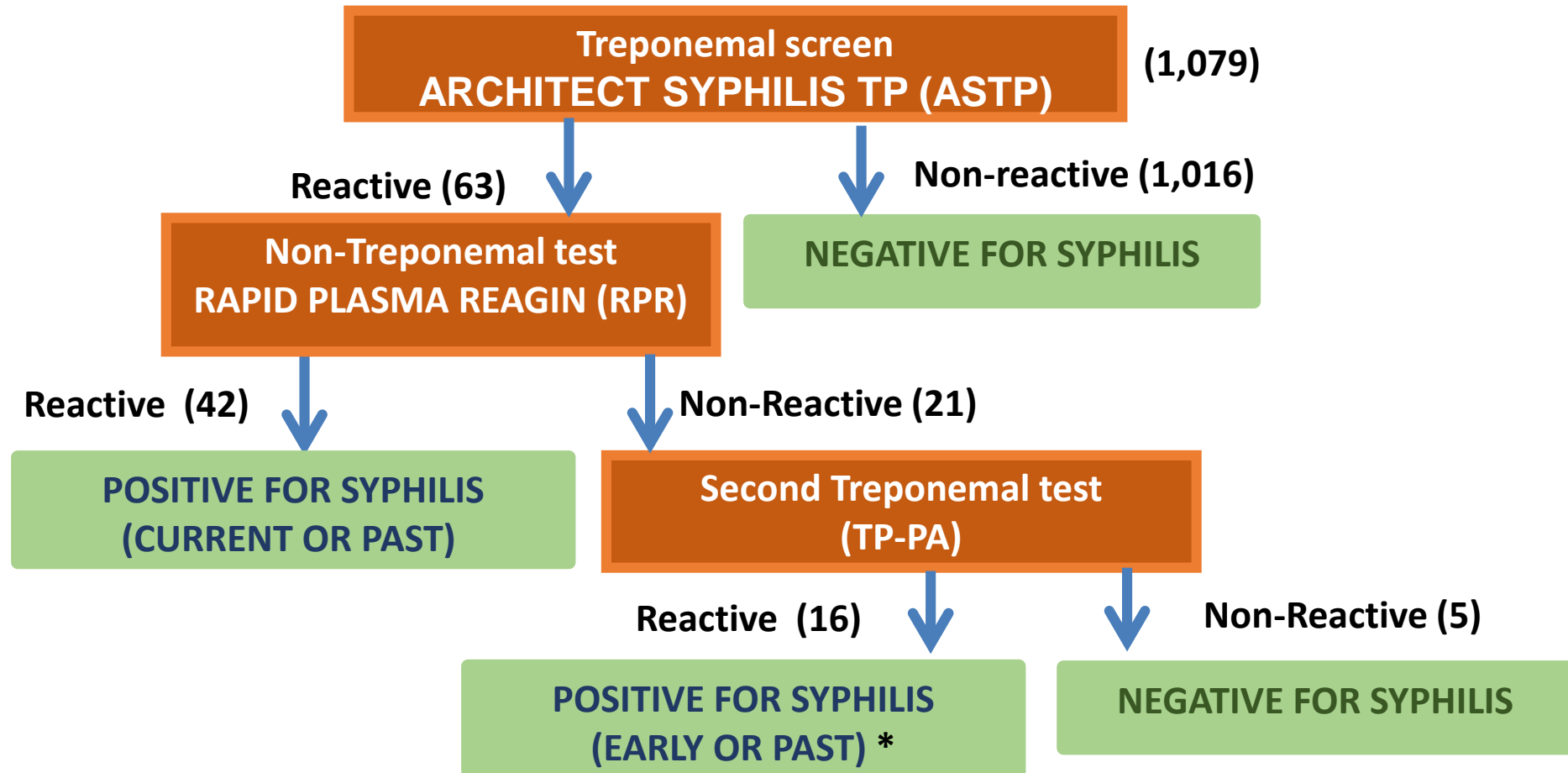
- Positive syphilis cases were determined by two concordant reactive treponemal tests OR one treponemal reactive and one non-treponemal reactive test.
- To differentiate between past/latent or early infections, clinical and treatment data from the **Florida Department of Health Surveillance Tools and Reporting System (STARS)*** database was reviewed.
 - If STARS did not indicate a latent, sero-fast or treated status, a positive syphilis case was classified as a P&S infection.



Traditional Algorithm Results



Reverse Algorithm Results



***P&S Infections, Treatment Naïve (11); Past Syphilis with Documented Care (5)**



Conclusion

Total = 1,079	Reverse Algorithm ASTP screen/RPR/TP-PA (95% CI)	Traditional Algorithm RPR screen/EIA/TP-PA (95% CI)
Positive syphilis cases (infectious and non- infectious), N=59	58/59 = 98.3% (95% - 100%)	43/59 = 72.9% (61.7% - 84.1%)
No laboratory evidence of syphilis, N=1020	1020/1020 = 100% (99.7% - 100%)	1017/1020 = 99.7% (99.3% - 100%)



Conclusion (cont.)

STARS review of the 42 cases positive in both Reverse and Traditional Algorithms:

- **11 were P&S infections**
- **31 were either latent (21) or past/ treated (9) or sero-fast (1)**

STARS review of the 16 additional cases positive with Reverse Algorithm only:

- **11 were P&S infections**
- **5 were past syphilis (with documented linkage to care)**



Discussion

- **The Reverse Algorithm may identify as much as a 2-fold increase in P&S cases per year.**
- **Early detection and treatment averts new P&S syphilis cases and lowers healthcare costs, but transition to the Reverse Algorithm will result in higher analytical testing cost for the laboratory.**



Discussion (cont.)

To offset additional costs, the FBPHL plans to implement a “blended” syphilis algorithm:

- RPR only testing will be performed for individuals with history of syphilis or for treatment follow-up.
- Reverse Algorithm will be performed for routine syphilis screening (with signs/symptoms), prenatal, neonatal and contact cases.



Discussion (cont.)

Barriers to Implementation of a “blended” syphilis algorithm:

- **Fiscal concerns – difficult to forecast how many RPR only vs. Reverse Algorithm tests will be ordered by providers.**
- **IT issues – extensive changes required for ELO by providers and ELR by the laboratory.**
- **Need for provider notification about the algorithm change and guidance to end users as to how and when to order appropriate test(s).**





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