Independent Performance Evaluation

Comparative Evaluations of Atellica, ARCHITECT, and COBAS Treponema-Specific Antibody Assays

Borae G. Park, Jihoon G. Yoon, John Hoon Rim, et al. Comparison of six automated treponema-specific antibody assays. Journal of Clinical Microbiology. 2016. doi:10.1128/JCM.02593-15

Why it matters

- Serology testing aids in syphilis diagnosis and includes assays for treponemal and nontreponemal antibodies.
- For syphilis serologic testing, the U.S. Centers for Disease Control and Prevention (CDC) recommends the traditional "screening" algorithm (initial screening with nontreponemal assays) or the reverse "screening" algorithm (initial screening with treponemal immunoassays).[1] If the initial screening is reactive, the other assay type (treponemal assay for the traditional algorithm and nontreponemal assay for the reverse algorithm) should be used.
- A study that evaluated the performance of automated treponemal-specific immunoassays with sera from patients with and without syphilis is described here.

What it covers

- International syphilis standards (n=2), leftover serum samples (n=613)
  - 329 samples from patients with suspected current or previous syphilis
- Treponemal-specific immunoassays included ADVIA Centaur Syphilis, Abbott ARCHITECT Syphilis TP, and Roche COBAS Syphilis. Fluorescent treponemal antibody absorption (FTA-ABS) test was the comparator.

Highlights

- When each assay was compared with FTA-ABS, the percent agreement for the ADVIA Centaur Syphilis assay was comparable to those of Abbott ARCHITECT Syphilis TP and Roche COBAS Syphilis (Table 1).
- This comparability in percent agreement was apparent despite differences in the number of antigen sources for each assay (Table 1).
- ADVIA Centaur and Atellica IM systems use the same reagent formulations and their syphilis assays have a positive percent agreement and negative percent agreement of 100% each (Table 2).[2] Hence, it is expected that the Atellica IM Syphilis (Syph) assay would yield results similar to those of the ADVIA Centaur Syphilis assay.

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Table 1. Comparison of the performance of automated treponemal-specific syphilis assays[a]

Assay	FTA-ABS Results		% Agreement	Antigen Sources for Assay
	No. of Reactive	No. of Nonreactive		
ADVIA Centaur				
No. of Reactive	156	0	99.8	TpN15 and TpN17
No. of Nonreactive	1	458		
Abbott ARCHITECT				
No. of Reactive	152	0	99.2	TpN15, TpN17 and TpN47
No. of Nonreactive	5	458		
Roche COBAS				
No. of Reactive	156	0	99.8	TpN15, TpN17 and TpN47
No. of Nonreactive	1	458		

[a] *Each assay was compared with FTA-ABS to determine percent agreement.*

Table 2. Atellica IM Syphilis assay vs. ADVIA Centaur Syphilis assay[2]

Positive Percent Agreement of Atellica IM Syphilis assay vs. ADVIA Centaur Syphilis assay			
Number	**Nonreactive**	**Reactive**	**Positive Percent Agreement**
107	0	107	100% (107/107)
Negative Percent Agreement of Atellica IM Syphilis Assay vs. ADVIA Centaur Syphilis assay			
Number	**Nonreactive**	**Reactive**	**Negative Percent Agreement**
123	123	0	100% (123/123)

The "screening" term expressed throughout this paper represents solely the opinion of the authors and should not be attributed to Siemens Healthineers. The ADVIA Centaur and Atellica IM Syphilis assays from Siemens Healthineers are not intended for use in general screening. Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings as an aid in the diagnosis of syphilis.

References:

1. Papp, JR et al. CDC laboratory recommendations for syphilis testing, United States, 2024. MMWR Recomm Rep. 2024;73(No. RR-1):1-32. doi: 10.15585/mmwr.rr7301a1
2. Atellica IM Syphilis assay package insert. Siemens Healthcare Diagnostics Inc. 10995423_EN Rev. 05, 2020-08

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