

Independent Performance Evaluation

Comparative Evaluations of Atellica, ARCHITECT, COBAS, LIAISON, and BIOPLEX 2200 Treponema-Specific Antibody Assays

Study 1. Bora 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

Study 2. Ina U. Park, Yetunde F. Fakile, Joan M. Chow, et al. Performance of treponemal tests for the diagnosis of syphilis. *Clinical Infectious Diseases*. 2019. doi:10.1093/cid/ciy558



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.
- Similar testing recommendations to the CDC exist outside the U.S. The 2020 European guidelines support both traditional and reverse testing, but comment that reverse testing may provide both earlier primary and increased late latent disease detection.²
- Two studies that evaluated the performance of automated treponemal-specific immunoassays with sera from patients with and without syphilis are described here.

What it covers

Study 1:

- 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.

Study 2:

- Remnant serum samples (n=959) from three institutions in California (2012-2013)
 - 556 samples from patients with current or prior syphilis
- ADVIA Centaur Syphilis assay, Bio-Rad BIOPLEX 2200 Syphilis IgG assay, and Diasorin LIAISON Treponema Screen were included.
- Sensitivity and specificity were analyzed in Study 1 and Study 2

Highlights

- When each assay was compared with FTA-ABS (reference standard), the ADVIA Centaur Syphilis assay had sensitivity and specificity comparable to those of Abbott ARCHITECT Syphilis TP and Roche COBAS Syphilis in Study 1 (Table 1). In Study 2, which used a clinical reference standard, comparable sensitivity and specificity were observed for the ADVIA Centaur Syphilis assay, Bio-Rad BIOPLEX 2200 Syphilis IgG, and Diasorin LIAISON Treponema Screen (Table 1).
- This comparability in sensitivity and specificity was apparent in Study 1 and Study 2 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 relative sensitivity and specificity of 100% each (Table 2).³ Hence, it is expected that the Atellica IM Syphilis (Syph) assay would yield results similar to those of the ADVIA Centaur Syphilis assay.

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

| Assay | Antigen Sources for Assay | Sensitivity, % n=157 | Specificity, % n=458 |
|----------------------------|---|-------------------------|-------------------------|
| Study 1^a | | | |
| ADVIA Centaur | TpN15 and TpN17 | 99.4 | 100.0 |
| Abbott ARCHITECT | TpN15, TpN17 and TpN47 | 96.8 | 100.0 |
| Roche COBAS | TpN15, TpN17 and TpN47 | 99.4 | 100.0 |
| Assay | Antigen Sources for Assay | Sensitivity, % n=262 | Specificity, % n=403 |
| Study 2^b | | | |
| ADVIA Centaur | TpN15 and TpN17 | 97.3 | 95.5 |
| Diasorin LIAISON | TpN17 | 96.9 | 94.5 |
| Bio-Rad BIOPLEX 2200 | Tp17 and Tp47/ cardiolipin, lecithin, cholesterol | 96.9 | 96.7 |

^a Each assay in Study 1 was compared with FTA-ABS to determine relative sensitivity and specificity.

^b The combination of serology results and clinical diagnosis in patients' electronic medical records served as the reference standard in Study 2.

Table 2. Atellica IM Syphilis assay vs. ADVIA Centaur Syphilis assay³

| Relative sensitivity of Atellica IM Syphilis assay vs. ADVIA Centaur Syphilis assay | | | |
|---|-------------|----------|----------------------|
| Number | Nonreactive | Reactive | Relative Sensitivity |
| 107 | 0 | 107 | 100% (107/107) |
| Relative specificity of Atellica IM Syphilis Assay vs. ADVIA Centaur Syphilis assay | | | |
| Number | Nonreactive | Reactive | Relative Specificity |
| 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.

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Siemens Healthineers Headquarters
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Published by
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