Performance Evaluation of the ADVIA Centaur and Atellica IM Zika Tests


Abstract
Background: Siemens Healthineers ADVIA Centaur® and Atellica IM Zika Tests are fully automated, immunoassay-based tests for Zika virus in serum and plasma. The ADVIA Centaur and Atellica IM Zika Tests are each comprised of two assays: (2) Zika Ab and (2) Zika IgM. Zika virus IgM antibodies are used to determine the presence of anti-Zika virus IgM antibodies. Both assays are used to detect chimeric immune responses.

Methods: The performance of each of the ADVIA Centaur Zika test and the Atellica IM Zika Tests was evaluated using serial dilution samples obtained from Zika virus PCR-positive individuals, non-endemic samples collected from normal donors (US) and pregnant women (US), and endemic samples collected from symptomatic (Dominican Republic) and asymptomatic (Dominican Republic and Honduras) individuals. Performance of the ADVIA Centaur Zika test on the ADVIA Centaur XP Immunoassay System was compared with previously published work. In a separate large cohort of non-endemic population including healthy, pregnant, and travelers, the Atellica IM Zika Test was evaluated with potentially cross-reactive samples. Precision and interference with common endogenous substances were assessed.

Results: The ADVIA Centaur and Atellica IM Zika Test algorithm determines the presence of IgM antibodies to the Zika virus (Figure 1).</p>

**Methods**

**Zika Ab and Zika IgM assay:**

- **Zika Ab** assay determines the presence of IgM antibodies to the Zika virus (Figure 1).
- **Zika IgM** assay measures the presence of Zika IgM antibodies in the serum and plasma of Zika virus-infected individuals.

**Advantages:**

- Full automation
- Rapid results
- High specificity and sensitivity

**Disadvantages:**

- Requires serum or plasma
- Limited availability

**Conclusion:**

The ADVIA Centaur and Atellica IM Zika Tests are fully automated, immunoassay-based tests for Zika virus in serum and plasma. The ADVIA Centaur and Atellica IM Zika Tests are each comprised of two assays: (2) Zika Ab and (2) Zika IgM. Zika virus IgM antibodies are used to determine the presence of anti-Zika virus IgM antibodies. Both assays are used to detect chimeric immune responses.

**Results:**

- **Sensitivity:** The ADVIA Centaur and Atellica IM Zika Tests showed 100% positive agreement with the ADVIA Centaur Zika Test when tested with Zika-positive serial draw samples (Table 10).
- **Specificity:** The Atellica IM Zika Test was nonreactive in all 20 Zika-negative individuals tested and showed 100% positive agreement with the ADVIA Centaur Zika Test when tested with Zika-negative serial draw samples (Table 10).

**Conclusion:**

The ADVIA Centaur and Atellica IM Zika Tests are fully automated, immunoassay-based tests for Zika virus in serum and plasma. The ADVIA Centaur and Atellica IM Zika Tests are each comprised of two assays: (2) Zika Ab and (2) Zika IgM. Zika virus IgM antibodies are used to determine the presence of anti-Zika virus IgM antibodies. Both assays are used to detect chimeric immune responses.