FDA is supporting Zika diagnostic test development. Zika virus may have serious implications for certain populations. A positive Zika test result can pose a serious and challenging situation for pregnant women.

It is essential that in vitro diagnostic tests for Zika virus provide accurate and reliable results.

2 TYPES OF TESTS

- To determine if people exposed to Zika were infected
- To diagnose acute Zika infection

Nucleic acid (NAT)-based in vitro diagnostics (IVDs) are designed to detect acute Zika infection.

Test sensitivity may vary considerably for different NAT IVDs. Manufacturers need standardized reference materials.

REFERENCE MATERIALS

FDA has created the FDA Zika Virus Reference Material for NAT-Based Zika IVD Devices.

Viral RNA:
- 2 Zika strains
- 3 controls

For Zika diagnostic test manufacturers, it is essential that in vitro diagnostic tests provide accurate and reliable results.

FDA is asking test manufacturers to assess traceability of Zika detection devices with the FDA Zika Virus Reference Material for NAT-Based Zika IVD Devices that have a pre-EUA submission with FDA.

To request the FDA Verification Panel, email: CDRH-ZIKA-Templates@fda.hhs.gov

More about FDA’s Zika response:
www.fda.gov/medicalcountermeasures