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.

TESTS NEEDED

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

2 TYPES OF TESTS

NAT

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

Compare test results to ENSURE ACCURACY

Viral RNA:
2 Zika strains
3 controls

REFERENCE MATERIALS

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

FOR ZIKA DIAGNOSTIC TEST MANUFACTURERS

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

U.S. FOOD & DRUG ADMINISTRATION

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