

EUA Sponsorship

- Driven by market forces and need to stockpile the product
 - Who is the customer?
 - Where will the product be stored?
 - Is there a declared emergency?
 - Is there a commercial market for the product?
- Government or Industry Sponsor
 - USG: Drugs/biologics held and deployed by SNS, or government-manufactured MCMs
 - Industry: Most EUAs for Zika diagnostics



Current EUAs for BARDA Zika Program Portfolio

Test	EUA status
InBios ZIKV Detect IgM Capture ELISA	EUA issued August 17, 2016, amended March 27, 2017, second amendment May 18, 2018
InBios ZIKV Detect IgM Diagnostic	Currently conducting studies to support EUA
ChemBio DPP Zika IgM Assay System	EUA issued September 27, 2017, EUA amended August 3, 2018
OraSure OraQuick Zika Diagnostic	Currently conducting studies to support EUA
DiaSorin Zika Diagnostic	EUA issued April 5, 2017, v2 ELISA EUA issued May 21, 2018
Siemens Zika Diagnostic	EUA issued September 18, 2017, EUA amended November 18, 2017

