



Co-Dx Logix Smart™ ZIKV

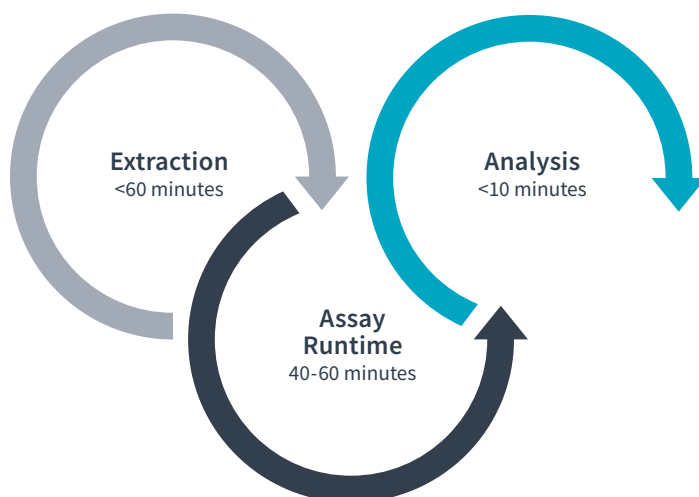
Innovating Molecular Diagnostic Solutions

Co-Dx Logix Smart™ ZIKV is a real-time CE-IVD PCR test used to detect the presence or absence of Zika virus through extracted ribonucleic acid (RNA) from serum or plasma collected along with matching urine sample from symptomatic or asymptomatic patients, suspected or exposed to Zika virus, which includes patients that had unprotected sex with a partner that travelled to or lives in an endemic area with high risk of Zika virus exposure. According to CDC, Real-time PCR technology is the preferred method when testing for Zika (CDC, 2017) due to its higher sensitivity and specificity when compared to other technologies.

Logix Smart™ ZIKV offers a rapid, accurate, and inexpensive molecular diagnostic test for Zika. Logix Smart™ ZIKV has been validated with QIAamp RNA Mini (QIAGEN) extraction kit and run in the Co-Dx Box™ instrument. For more information on other machines and extraction systems contact Co-Diagnostics, Inc.

Co-Dx Logix Smart™ ZIKV

- Compatible with multiple sample types
- Contains a simple and streamlined work flow
- Includes internal control to verify sample quality
- Includes positive control
- Produces results that are easy to interpret
- Compatible with multiple platforms & sample extraction techniques



Product Performance Characteristics

Application	Qualitative PCR test, screening		
	Specimen	Strain	Claimed LOD
Limit of detection	Serum	Asian lineage (PRVABC59, whole virus)	3.54×10 ⁴ copies/mL
	Urine	Asian lineage (MR766, RNA extract) African (MR766, RNA extract)	3.0×10 ⁴ copies/mL 1.3×10 ⁵ copies/mL
Sensitivity	98.8%		
Specificity	100%		
Sample type	Serum or plasma collected along with urine		
Detection details	Presence/absence of Zika virus		
Time to detection	63-90 minutes, depending on the machine used		
Thermal cycler compatibility	Most qPCR systems capable of the following channel compatibilities: FAM CF560 (VIC)		

† Results based on a total of 2441 contrived samples run on the CoDx Box™.

Each Co-Dx Logix Smart™ ZIKV kit includes:

- 1×500 µL (100rxns) Logix Smart™ ZIKV Master Mix
- 1×500 µL (100rxns) Logix Smart™ ZIKV Positive Control
- 1×500 µL (100rxns) Nuclease Free Water

Ordering Information:

Product Name	Product ID
Co-Dx Box™ Thermal Cycler	Request quote
Co-Dx Logix Smart™ ZIKV kit	ZIKV-K-004

The performance data of Logix Smart™ ZIKV was evaluated for precision, limit of detection, diagnostic accuracy, and analytical specificity testing to include the most relevant strains (inclusivity) of Zika. Specificity was also tested to exclude cross-reactivity with other flaviviruses, febrile and rash like diseases. Logix Smart™ ZIKV did not cross-react with any of the described microorganisms. Cross-reactivity for most relevant interfering substances natural for the recommended specimen have also been tested. The only relevant interference was found with the well-known PCR inhibitor, Heparin. For this reason, blood collection for use with Logix Smart™ ZIKV should be performed in non-Heparin and EDTA-free tubes.

References

CDC. (2017, Jul 24). Zika Virus: Guidance for US Laboratories Testing for Zika Virus Infection. Retrieved Feb 28, 2019, from Centers for Disease Control and Prevention: <http://www.cdc.gov/zika/laboratories/lab-guidance.html>