

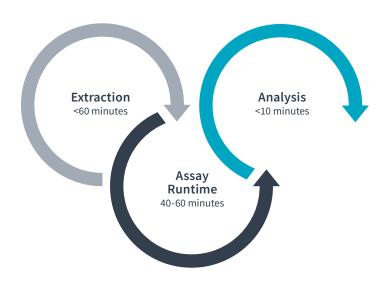
## Co-Dx Logix Smart™ ZDC

Innovating Molecular Diagnostic Solutions

Co-Dx Logix Smart™ ZDC is a real-time CE-IVD PCR multiplex test intended to detect Zika, dengue (types 1, 2, 3, and 4), and chikungunya viruses through extracted ribonucleic acid (RNA) from serum, plasma, CSF, and urine from symptomatic or asymptomatic patients. According to CDC, Real-time PCR technology is the preferred method when testing for these arboviruses due to its higher sensitivity and specificity when compared to other technologies (CDC, Division of Vector-Borne Diseases, 2016). Logix Smart™ ZDC offers a rapid, accurate, and inexpensive molecular diagnostic test to help in the global fight against these mosquito-borne diseases.

Logix Smart<sup>™</sup> ZDC has been validated with the QIAamp RNA Mini (QIAGEN) extraction kit and run in the Co-Dx Box<sup>™</sup> instrument, for more information on other machines and extraction systems contact Co-Diagnostics, Inc.

- 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 Multiplex PCR test, screening for ZIKV, DENV (types 1,2,3 and 4) and CHIKV				
Limit of detection	Markers	Specimen	Strain		Claimed LOD
	ZIKV	Plasma	Asian lineage (PRVABC59, whole virus)		1.52×10⁴ copies/mL
		Serum	Asian lineage (PRVABC59, RNA extract)		3.19×10⁴ copies/mL
		Urine			6.23×10⁴ copies/mL
		CSF (cerebrospinal fluid)			4.83×10⁴ copies/mL
	DENV	Plasma	DENV 1 (synthetic template)		8.21×10 <sup>4</sup> copies/mL
			DENV 1 (Hawaii, whole virus)		4.03×10 <sup>2</sup> PFU/mL
			DENV 2 (New Guinea C, RNA extract)		9.08×10⁴ copies/mL
			DENV 2 (New Guinea C, whole virus)		7.27×10 PFU/mL
			DENV 3 (H87, RNA extract)		5.05×10⁴ copies/mL
			DENV 3 (H87, whole virus)		1.91×10² copies/mL
			DENV4 (H241, RNA extract)		2.69×10⁵ copies/mL
			DENV4 (H241, whole virus)		6.13×10 <sup>2</sup> PFU/mL
	CHIKV	Serum	S27 Petersfield, RNA extract		1.03×10³ copies/mL
		Plasma	ECSA lineage, (WHO reference strain, R91064, whole virus)		4.27×10³ copies/mL
Diagnostic Sensitivity		Serum	Plasma	Urine	CSF
	ZIKV†	97.2%	93.2%	91.4%	96.0%
	DENV†	98.0%	99.3%	Not Performed	Not Performed
	CHIKV†	99.0%	94.4%	Not Performed	Not Performed
Diagnostic Specificity	ZIKV†	100%	100%	100%	100%
	DENV†	100%	100%	Not Performed	Not Performed
	CHIKV†	100%	100%	Not Performed	Not Performed
Specimen	ZIKV: Plasma, serum, urine, and CSF. DENV and CHIKV: serum and plasma.				
Genotype detection	None (including no differentiation of Dengue types 1, 2, 3, or 4)				
Detection details	Detection and differentiation of Zika, Dengue, and Chikungunya viruses.				
ime 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) CF610(ROX) Quasar670(Texas Red)				

<sup>†</sup> Results based on 4,853 contrived samples extracted using QIAamp RNA Mini kit and run on the CoDx Box™. Note: ZIKV, Zika virus; DENV, dengue virus; CHIKV, chikungunya virus.

## Each Co-Dx Logix Smart™ ZIKV kit includes:

1×500 μL (100rxns) Logix Smart™ ZDC Master Mix 1×500 μL (100rxns) Logix Smart™ ZDC Positive Control

 $1\times500~\mu L$  (100rxns) Nuclease Free Water

## **Ordering Information:**

Product Name	Product ID
Co-Dx Box™ Thermal Cycler	Request quote
Co-Dx Logix Smart™ ZDC kit	ZDC-K-001