

EDX Zika Verification Panel Summary	
Catalog Number	ZKVP100
Analyte	Inactivated Zika Virus
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-70°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Single Use
Shelf Life	36 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

**INTENDED USE:**

The EDX Zika Verification Panel is a standard for various molecular assays. EDX Zika Verification Panel is used to establish points of reference (qualitative and quantitative) for the measurement of Zika Virus RNA. EDX Zika Verification Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

**PRODUCT DESCRIPTION:**

The EDX Zika Verification Panel contains whole, intact virus that has been heat inactivated. EDX Zika Verification Panel is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX Zika Verification Panel is reported in copies per milliliter (cp/mL). EDX Zika Verification Panel is value assigned by digital droplet PCR and manufactured according to ISO 17511:2003. EDX Zika Verification Panel is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, Zika Virus RNA, HBsAg and antibodies for HIV-1/2 and HCV.

EDX Zika Components	Concentration
EDX Zika Panel Member 1	100 cp/mL
EDX Zika Panel Member 2	1,000 cp/mL
EDX Zika Panel Member 3	10,000 cp/mL
EDX Zika Panel Member 4	100,000 cp/mL
EDX Zika Panel Member 5	1,000,000 cp/mL

**PROCEDURE:**

The EDX Zika Verification Panel requires an extraction step. The panel must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique. EDX Zika Verification Panel is to be tested according to the assay manufacturer’s or testing laboratory’s instructions and recommendations.

**STORAGE AND HANDLING:**

The EDX Zika Verification Panel should be stored at -70°C or below.

Thaw EDX Zika Verification Panel at room temperature and vortex briefly prior to use.

Once thawed, EDX Zika Verification Panel is stable for 24 hours when stored at 2-8°C. Any remaining materials must be disposed of after one use. Do not reuse. Do not dilute.

Do not use EDX Zika Verification Panel beyond the expiration date.

**LIMITATIONS:**

For In Vitro Diagnostic Use.

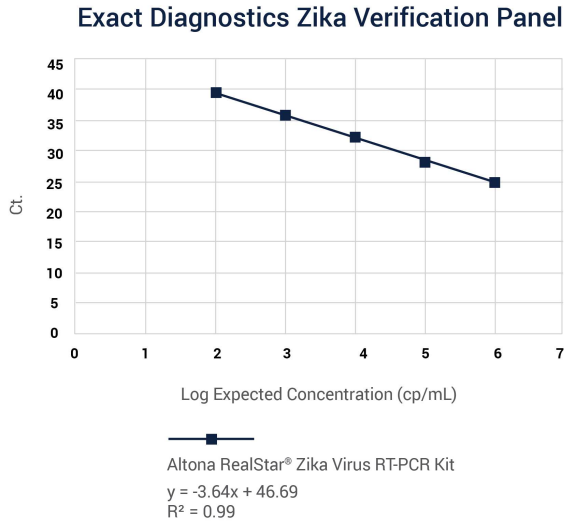
**WARNINGS AND PRECAUTIONS:**

The EDX Zika Verification Panel contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced<sup>1</sup>. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contain pathogenic agents.

**PERFORMANCE CHARACTERISTICS:**

Three unique lots of EDX Zika Verification Panel were tested in triplicate across the assay identified in the graph below.



The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

**REFERENCES:**

<sup>1</sup>Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

**SYMBOL REFERENCES:**



Catalog Number



Lot Number



For In Vitro Diagnostic Use



Biological Risks



Expiration Date



Do not re-use



Upper Limit of Temperature



Manufacturer



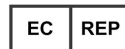
Caution



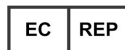
Consult Instructions for Use



European Mark of Conformity



Authorized Representative



Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands



Exact Diagnostics LLC  
3400 Camp Bowie Blvd CBH-214  
Fort Worth Texas 76107  
United States