

EDX VZV Verification Panel Summary	
Catalog Number	VZVP100
Analyte	Inactivated VZV
Matrix	Synthetic CSF Matrix
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Single Use
Shelf Life	24 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	In Vitro Diagnostic Use

EDX VZV Components	Concentration
EDX VZV Panel Member 1	500 cp/mL
EDX VZV Panel Member 2	2,000 cp/mL
EDX VZV Panel Member 3	20,000 cp/mL
EDX VZV Panel Member 4	200,000 cp/mL
EDX VZV Panel Member 5	2,000,000 cp/mL

PROCEDURE:

The EDX VZV 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.

The VZV Verification Panel is formulated in Synthetic CSF Matrix but can be diluted 1:1 in NEG050, Exact Diagnostics Bulk Negative, which is True EDTA Plasma. Expected concentration values from the table above will be reduced by 50% for the diluted panel. EDX VZV Verification Panel is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX VZV Verification Panel should be stored at -20°C or below.

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

Once thawed, EDX VZV 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 use EDX VZV Verification Panel beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX VZV Verification Panel contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced¹. 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.

INTENDED USE:

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

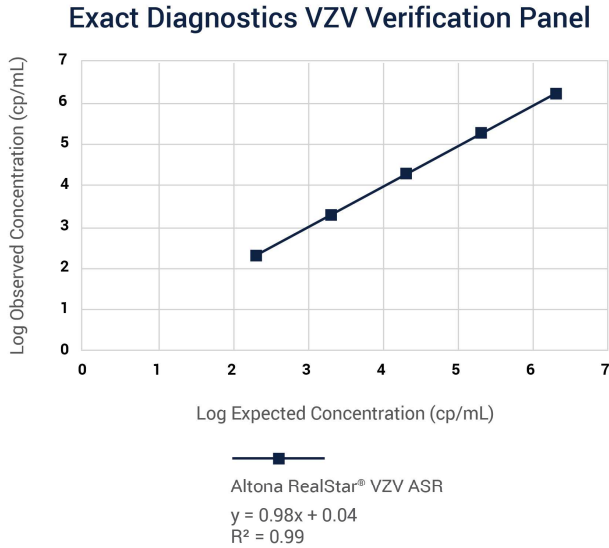
PRODUCT DESCRIPTION:

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

The EDX VZV Verification Panel is reported in copies per milliliter (cp/mL). The EDX VZV Verification Panel is value assigned by digital droplet PCR and manufactured according to ISO 17511:2003. EDX VZV Verification Panel is formulated in Synthetic CSF Matrix, which contains preservatives.

PERFORMANCE CHARACTERISTICS:

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















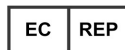
The data provided is for informational use only. Expected results must be established by the end user for the particular assay system used.

REFERENCES:

¹ 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:

-  REF Catalog Number
-  LOT Lot Number
-  IVD 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
-  EC REP Authorized Representative



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