

EDX CMV Verification Panel 1.4mL Summary	
Catalog Number	CMVP200
Analyte	Inactivated CMV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.6mL
Number of Vials Per Kit	6 Vials
Number of Uses	Single Use
Shelf Life	24 Months from Date of Manufacture
Traceability	1 st WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX CMV Verification Panel 1.4mL is a standard for various molecular assays. EDX CMV Verification Panel 1.4mL is calibrated against the 1st WHO International Standard for Cytomegalovirus (09/162)¹. EDX CMV Verification Panel 1.4mL is used to establish points of reference (qualitative and quantitative) for the measurement of Cytomegalovirus (CMV) DNA. EDX CMV Verification Panel 1.4mL allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX CMV Verification Panel 1.4mL contains whole, intact virus. EDX CMV Verification Panel 1.4mL is developed using heat inactivated CMV Merlin strain. EDX CMV Verification Panel 1.4mL is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX CMV Verification Panel 1.4mL is reported in International Units per milliliter (IU/mL). EDX CMV Verification Panel 1.4mL is value assigned by digital droplet PCR and manufactured according to ISO 17511:2003. EDX CMV Verification Panel 1.4mL is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, CMV DNA, HBsAg and antibodies for HIV-1/2 and HCV.

EDX CMV Components	Concentration
EDX CMV Panel Member 1	200 IU/mL
EDX CMV Panel Member 2	400 IU/mL
EDX CMV Panel Member 3	4,000 IU/mL
EDX CMV Panel Member 4	40,000 IU/mL
EDX CMV Panel Member 5	400,000 IU/mL
EDX CMV Panel Member 6	4,000,000 IU/mL

PROCEDURE:

The EDX CMV Verification Panel 1.4mL 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 CMV Verification Panel 1.4mL is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX CMV Verification Panel 1.4mL should be stored at -20°C or below.

Thaw EDX CMV Verification Panel 1.4mL at room temperature and vortex briefly prior to use.

Once thawed, EDX CMV Verification Panel 1.4mL 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 CMV Verification Panel 1.4mL beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX CMV Verification Panel 1.4mL contains heat inactivated virus but should be considered biohazardous. Universal precautions and proper disposal should be practiced². 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.

REFERENCES:

¹The 1st WHO International Standard for Cytomegalovirus (09/162) IFU. <http://www.nibsc.org/documents/ifu/09-162.pdf>

²Siegel 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



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