

EDX CMV 5E5 IU/mL Precision Summary	
Catalog Number	CMVH202
Analyte	Inactivated CMV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.4mL
Number of Vials Per Kit	9 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 5E5 IU/mL Precision is calibrated against the 1st WHO International Standard for Cytomegalovirus (09/162)¹. EDX CMV 5E5 IU/mL Precision is used to determine the accuracy of the assay for the presence of Cytomegalovirus (CMV) DNA at the target concentration of 5E5 IU/mL. Routine use of EDX CMV 5E5 IU/mL Precision allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX CMV 5E5 IU/mL Precision contains whole, intact virus. EDX CMV 5E5 IU/mL Precision is developed using heat inactivated CMV Merlin strain. EDX CMV 5E5 IU/mL Precision is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX CMV 5E5 IU/mL Precision is reported in International Units per milliliter (IU/mL). EDX CMV 5E5 IU/mL Precision 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.

PROCEDURE:

The EDX CMV 5E5 IU/mL Precision requires an extraction step. The product must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique. EDX CMV 5E5 IU/mL Precision is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX CMV 5E5 IU/mL Precision should be stored at -20°C or below.

Thaw EDX CMV 5E5 IU/mL Precision at room temperature and vortex briefly prior to use.

Once thawed, EDX CMV 5E5 IU/mL Precision 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 5E5 IU/mL Precision beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX CMV 5E5 IU/mL Precision 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:

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

² 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


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