

EDX CMV Low Run Control	
Catalog Number	CMVL101
Analyte	Inactivated CMV Merlin Virus
Number of Vials Per Kit	5 Vials
Fill Volume	1.0mL
Traceability	1st WHO International Standard
Matrix	True EDTA Plasma
Precautions	Biological Risks
Storage	-20°C or Below
Shelf Life	18 months from date of manufacture
Regulatory Status	For In Vitro Diagnostic Use
Preservative	ProClin® 300

INTENDED USE:

EDX CMV Low Run Controls are a run control for various molecular assays, calibrated against the 1st WHO International Standard for cytomegalovirus (09/162)¹. The controls are used to monitor the presence of CMV DNA. The materials are whole, intact virus allowing operators to test the entire process of a molecular assay, train operators and test for proficiency.

PRODUCT DESCRIPTION:

EDX CMV Low Run Controls are intact whole virus that has been heat inactivated. The control is intended to test the entire process of a variety of molecular assays from extraction, detection, and amplification.

EDX CMV Low Run Controls are reported in International Units per milliliter (IU/mL). The controls are developed using heat inactivated CMV Merlin Virus. The EDX CMV Low Run Controls are formulated in True EDTA plasma that was not found to be reactive for HBV DNA, HCV RNA, HIV-1 RNA, HBsAg, and antibodies for HIV-1/2, and HCV.

PROCEDURE:

EDX CMV Low Run Controls are whole, intact virus and should be treated similarly as all other samples going through an extraction step, allowing the operator to assess their extraction technique. Test the EDX CMV Low Run Controls according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

EDX CMV Low Run Controls should be stored at -20°C or below.

Thaw material at room temperature and vortex briefly prior to use.

Once thawed, material is stable for 24 hours when stored at 2-8°C. Do not dilute. Product can be frozen and reused a maximum of four (4) times. After the 4th freeze thaw, any remaining materials must be disposed of.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

EDX CMV Low Run Controls contain heat inactivated virus, but should be considered biohazardous and 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.

REFERENCES:

¹ 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:



Catalog Number



Lot Number



For In Vitro Diagnostic Use



Biological Risks



Expiration Date



Upper Limit of Temperature



Manufacturer



Caution



Positive Control