

EDX CMV High Run Control Summary	
Catalog Number	CMVH102
Analyte	Inactivated CMV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Multiple Use
Shelf Life	36 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 High Run Control is an external quality control, intended to be used with CMV assays to monitor the performance of that given assay. EDX CMV High Run Control is calibrated against the 1st WHO International Standard for Cytomegalovirus (09/162)¹. The control is used to monitor the presence of cytomegalovirus (CMV) DNA. Routine use of EDX CMV High Run Control allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX CMV High Run Control contains whole, intact virus that have been heat inactivated. The control is intended to test the entire process of molecular assays including extraction, detection, and amplification.

EDX CMV High Run Control 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 High Run Control requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to monitor their extraction technique.

The EDX CMV High Run Control is an unassayed control and does not have assigned values. The control is not to be used as a substitute for the manufacturer's kit controls provided with the assay. EDX CMV High Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX CMV High Run Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX CMV High Run Control should be stored at -20°C or below.

Thaw EDX CMV High Run Control at room temperature and vortex briefly prior to use.

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

Do not use EDX CMV High Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX CMV High Run Control 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 contained pathogenic agents.

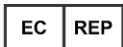
REFERENCES:

¹The 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
	Consult Instructions for Use
	Positive Control
	European Mark of Conformity
	Authorized Representative



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