

EDX HCV LOD Summary	
Catalog Number	HCVLOD
Analyte	Inactivated HCV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-70°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	10 Vials
Number of Uses	Single Use
Shelf Life	24 Months from Date of Manufacture
Traceability	4 th WHO International Standard
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX HCV LOD is calibrated against the 4th WHO International Standard for Hepatitis C (06/102)¹. EDX HCV LOD is used to determine the analytical sensitivity of the assay for Hepatitis C Virus (HCV) RNA. EDX HCV LOD allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

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

The EDX HCV LOD is formulated in True EDTA Plasma that is non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, HBsAg and antibodies for HIV-1/2, and HCV.

PROCEDURE:

The EDX HCV LOD requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

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

STORAGE AND HANDLING:

The EDX HCV LOD should be stored at -70°C or below.

Thaw EDX HCV LOD at room temperature and vortex briefly prior to use.

Once thawed, EDX HCV LOD 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 HCV LOD beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HCV LOD 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 4th WHO International Standard for Hepatitis C (06/102) IFU.
<http://www.nibsc.org/documents/ifu/06-102.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



Positive Control



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