

EDX HCV 1E6 IU/mL Precision Summary	
Catalog Number	HCVH202
Analyte	Recombinant HCV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.4mL
Number of Vials Per Kit	2 x 9 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 1E6 IU/mL Precision is calibrated against the 4th WHO International Standard for Hepatitis C (06/102)¹. EDX HCV 1E6 IU/mL Precision is used to determine the accuracy of the assay for the presence of Hepatitis C Virus (HCV) RNA at the target concentration of 1E6 IU/mL. Routine use of EDX HCV 1E6 IU/mL Precision allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX HCV 1E6 IU/mL Precision contains whole, intact virus that is non-infectious. EDX HCV 1E6 IU/mL Precision is developed using recombinant, non-infectious virus which contains the HCV 5' UTR insertion. EDX HCV 1E6 IU/mL Precision is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HCV 1E6 IU/mL Precision is reported in International Units per milliliter (IU/mL). EDX HCV 1E6 IU/mL Precision 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 1E6 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 HCV 1E6 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 HCV 1E6 IU/mL Precision should be stored at -20°C or below.

Thaw EDX HCV 1E6 IU/mL Precision at room temperature and vortex briefly prior to use.

Once thawed, EDX HCV 1E6 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 HCV 1E6 IU/mL Precision beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HCV 1E6 IU/mL Precision contains non-infectious HCV recombinant 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



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United States

Manufactured By: Exact Diagnostics LLC, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107

For assistance and reordering, contact customerservice@exactdiagnostics.com or **817.989.9262**

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