

EDX HCV Genotype Panel Summary	
Catalog Number	HCVGTP
Analyte	Inactivated HCV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	6 Vials
Number of Uses	Multiple Use
Shelf Life	18 Months from Date of Manufacture
Traceability	4 th WHO International Standard
Precautions	Biological Risks
Regulatory Status	For Research Use Only

INTENDED USE:

The EDX HCV Genotype Panel is to be used with HCV assays to monitor the performance of that given assay. EDX HCV Genotype Panel is calibrated against the 4th WHO International Standard for Hepatitis C (06/102)¹ which is Genotype 1. EDX HCV Genotype Panel is used to confirm the presence or absence of Hepatitis C Genotypes. EDX HCV Genotype Panel allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

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

The EDX HCV Genotype Panel 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.

EDX HCV Genotype Panel Components
EDX HCV Genotype 1a
EDX HCV Genotype 1b
EDX HCV Genotype 2
EDX HCV Genotype 3
EDX HCV Genotype 4
EDX HCV Genotype 5

PROCEDURE:

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

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

STORAGE AND HANDLING:

The EDX HCV Genotype Panel should be stored at -20°C or below.

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

Once thawed, EDX HCV Genotype Panel 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 fourth freeze thaw, any remaining materials must be disposed of.

Do not use EDX HCV Genotype Panel beyond the expiration date.

LIMITATIONS:

For Research Use Only. Not for use diagnostic procedures.

WARNINGS AND PRECAUTIONS:

The EDX HCV Genotype Panel 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).
<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 Research Use Only. Not for use in diagnostic procedures.



Biological Risks



Expiration Date



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



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Fort Worth, Texas 76104
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