

EDX HCV Verification Panel 1.4mL Summary	
Catalog Number	HCVP200
Analyte	Recombinant HCV
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.4mL
Number of Vials Per Kit	7 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 Verification Panel 1.4mL is a standard for various molecular assays. EDX HCV Verification Panel 1.4mL is calibrated against the 4th WHO International Standard for Hepatitis C (06/102)¹. EDX HCV Verification Panel 1.4mL is used to establish points of reference (qualitative and quantitative) for the measurement of Hepatitis C Virus (HCV) RNA. EDX HCV Verification Panel 1.4mL allows laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX HCV Verification Panel 1.4mL contains whole, intact virus. EDX HCV Verification Panel 1.4mL is developed using recombinant, non-infectious virus which contains the HCV 5' UTR insertion. EDX HCV Verification Panel 1.4mL is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX HCV Verification Panel 1.4mL is reported in International Units per milliliter (IU/mL). EDX HCV Verification Panel 1.4mL is manufactured according to ISO 17511:2003. EDX HCV Verification Panel 1.4mL 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 Components	Concentration
EDX HCV Panel Member 1	100 IU/mL
EDX HCV Panel Member 2	300 IU/mL
EDX HCV Panel Member 3	3,000 IU/mL
EDX HCV Panel Member 4	30,000 IU/mL
EDX HCV Panel Member 5	300,000 IU/mL
EDX HCV Panel Member 6	3,000,000 IU/mL
EDX HCV Panel Member 7	30,000,000 IU/mL

PROCEDURE:

The EDX HCV Verification Panel 1.4mL 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. EDX HCV Verification Panel 1.4mL is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

The EDX HCV Verification Panel 1.4mL should be stored at -20°C or below.

Thaw EDX HCV Verification Panel 1.4mL at room temperature and vortex briefly prior to use.

Once thawed, EDX HCV Verification Panel 1.4mL 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 Verification Panel 1.4mL beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX HCV Verification Panel 1.4mL 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).
<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:

-  REF Catalog Number
-  LOT Lot Number
-  IVD For In Vitro Diagnostic Use
-  Biological Risks
-  Expiration Date
-  Do not re-use
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  Consult Instructions for Use


Exact Diagnostics LLC
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
United States



**Bio-Rad
Laboratories**

**Clinical
Diagnostics Group**

9500 Jeronimo Road
Irvine, California 92618
(800) 854-6737
FAX (949) 598-1550
bio-rad.com/qualitycontrol

Technical Service:
(800) 854-6737

United States Customer Service: 4000 Alfred Nobel Drive • Hercules, California 94547 • Phone (510) 724-7000 • FAX (510) 741-6373
Also in: **Gladesville, Australia,** Phone +61 (2) 9914 2800 • Fax +61 (2) 9914 2888 **Vienna, Austria,** Phone +43 (0) 1 877 89 01 9 • Fax +43 (0) 1 876 56 29 **Temse, Belgium,** Phone +32 (0) 3 710 53 00 • Fax +32 (0) 3 710 53 01 **São Paulo, Brazil,** Phone +55 11 3065-7550 **Montréal, Canada,** Phone +1 514 334 4372 • Fax +1 514 334 0872 **Shanghai, China,** Phone +86 21 6169 8500 • Fax +86 21 6169 8599 **Prague, Czech Republic,** Phone +420 241 431 660 **Symbion Science Park, Denmark,** Phone +45 44 52 10 00 • Fax +45 44 52 10 01 **Helsinki, Finland,** Phone +358 9 804 22 00 **Marnes-la-Coquette, France,** Phone +33 (0) 1 47 95 60 00 • Fax +33 (0) 1 47 41 91 33 **Munich, Germany,** Phone +49 (0) 89 31884 393 • Fax +49 (0) 89 31884 136 **Athens, Greece,** Phone +30 210 7774396 • Fax +30 210 7774376 **Quarry Bay, Hong Kong,** Phone +85 2 2789 3300 • Fax +85 2 2789 1257 **Budapest, Hungary,** Phone +36 1 459 6190 • Fax +36 1 459 6101 **Haryana, India,** Phone +91 124 4029300 • Fax +91 124 2398115 **Rishon Le Zion, Israel,** Phone +972 03 963 6025 • Fax +972 03 951 4129 **Milan, Italy,** Phone +39 024 94 86 600 • Fax +39 02 21609399 **Tokyo, Japan,** Phone +81 3 6361 7070 • Fax +81 3 5463 8481 **Seoul, Korea,** Phone +82 080 007 7373 • Fax +82 (2) 3472 7003 **Mexico D.F., Mexico,** Phone +52 (55) 5488 7670 • Fax +52 (55) 1107 7246 **Veenendaal, The Netherlands,** Phone +31 (0)318 540 666 • Fax +31 (0)318 542 216 **Auckland, New Zealand,** Phone +64 (9)415 2280 • Fax +64 (9)415 2284 **Oslo, Norway,** Phone +47 23 38 41 30 • Fax +47 23 38 41 39 **Warsaw, Poland,** Phone +48 22 331 99 99 • Fax +48 22 331 99 88 **Amadora, Portugal,** Phone +351 21 47 27 700 • Fax +351 21 472 7777 **Moscow, Russia,** Phone +7 495 721 1404 • Fax +7 495 721 1412 **Singapore,** Phone +65 6415 3170 • Fax +65 6415 3189 **Johannesburg, South Africa,** Phone +27 11 442 8508 • Fax +27 11 442 8525 **Madrid, Spain,** Phone + 34 91 490 6580 • Fax +34 91 590 5211 **Sundbyberg, Sweden,** Phone +46 844 98053 • Fax +46 8 55 51 27 80 **Cressier, Switzerland,** Phone +41 (0) 61 717 9555 • Fax +41 (0) 61 717 9550 **Taipei, Taiwan,** Phone +886 (2) 2578-7189 • Fax +886 (2) 2578-8890 **Bangkok, Thailand,** Phone (662) 651 8311 • Fax (662) 651 8312 **Hertfordshire, United Kingdom,** Phone +44 (0)1923 471301 • Fax +44 (0)1923 471340