Hepatitis C Virus (HCV) Genotype Panel
Part Number: KZMC049
Lot Number: 1804-272-00007

These reagents are not a substitute for the mandatory positive and negative control reagents provided with licensed test kits.
For Research Use Only. Not for use in diagnostic procedures.

NAME AND INTENDED USE:
The HCV Genotype Panel is intended for use with assays in the determination of the HCV Genotypes. This panel is for R**esearch Use Only** and should not be used in diagnostic procedures.

SUMMARY:
The HCV Genotype Panel is composed of fourteen members representing a variety of genotypes. Each panel member is prepared from citrated human plasma. This panel can be used for training, lot-to-lot comparison of reagent test kits and to evaluate and compare intra laboratory and inter laboratory performance of HCV genotyping assays.

PRINCIPLES OF THE PROCEDURE:
Panel reagents have been designed for use with *in vitro* assay procedures for the purpose of monitoring assay performance across a range of HCV genotypes. Panel reagents are prepared from unadulterated human source plasma. The HCV Genotype Panel members should be evaluated as unknown specimens per the instructions supplied by the manufacturer of the test kit being used.

REAGENTS:
1. Two vials HCV Genotype, negative for HCV Antibody and HCV Nucleic Acid Testing, without HCV genotype (0.5mL).
2. Twelve vials HCV Genotype, positive for HCV Antibody and/or HCV Nucleic Acid Testing with data indicating HCV genotype (0.5 each).

WARNINGS AND PRECAUTIONS:

1. **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.**

2. **USE UNIVERSAL PRECAUTIONS: HANDLE AS IF CAPABLE OF TRANSMITTING INFECTIOUS AGENTS.**

HCV Genotype Panel reagents are prepared from unadulterated normal human plasma and unadulterated human plasma positive for HCV. All normal human plasma used in the preparation of HCV Genotype Panel reagents has been tested using FDA cleared assays and found non-reactive for HIV, HBsAg and HCV Ab. However, no known test method can assure that products derived from human sources will not transmit infection. It is recommended that these reagents and all human specimens be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH publication, Biosafety in Microbiological and Biomedical Laboratories (1), or other equivalent guidelines (2,3).

SAFETY PRECAUTIONS:
1. Clean any spillage immediately and thoroughly using a suitable disinfectant such as 1% bleach solution.
2. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents (1-3).

HANDLING PRECAUTIONS:
1. Do not use Panel reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and dispensing.

STORAGE INSTRUCTIONS:
1. Store unopened Panel reagents at -10 to -20°C when not in use.
2. Store opened Panel reagents at 2 to 8°C when not in use.
3. Vials should be stored upright to prevent leakage.
4. When stored as directed, Panel reagents are suitable for use for up to 60 days after opening.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION:
Alterations in physical appearance may indicate instability or deterioration of Panel reagents. Solutions which are visibly turbid should be discarded.

PROCEDURE:
1. Panel reagents may be included in a test run following the procedure provided by the test kit manufacturer for unknown specimens.
2. Allow Panel reagents to reach room temperature (15-30°C) prior to use. Return to proper storage after use.
3. Mix contents by gentle swirling prior to use. Do not mix by vigorous shaking, avoid foaming.

INTERPRETATION OF RESULTS:
Panel reagent test results should be determined as recommended for unknown specimens in the package insert for each commercially available test kit.

LIMITATION OF THE PROCEDURE:
1. Panel reagents must not be substituted for the positive and negative control reagents provided with commercially available test kits.
2. Panel reagents are provided for R**esearch Use Only** and must not be used for calibration or as primary reference preparations for any test kit.
3. PROCEDURE and INTERPRETATION OF RESULTS provided in package insert of each commercially available test kit must be followed closely when testing the Panel reagents. Deviations from the recommended procedures may produce unreliable results.
4. It is the responsibility of each laboratory to determine the suitability of Panel reagents for its particular use. They also must establish guidelines for the interpretation of results.

SPECIFIC PERFORMANCE CHARACTERISTICS:
The Panel reagents were tested using commercially available test systems following the procedures provided by the manufacturer for the testing of unknown specimens. The data contained in this document is intended to be representative of typical test procedures and should be used for informational use only. Each laboratory should establish its own performance characteristics.

PIKZMC049 Rev01
Effective Date:04/02/2020

This Product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.
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Representative Levels of Reactivity
Hepatitis C Virus (HCV) Genotype Panel
Expiration Date: 01/24/2022

Panel Member	HCV Genotype LIPA Test Date: UNK	Roche Cobas Real Time PCR (IU/mL) Test Date: UNK	Ortho ECi A-HCV Test Date: 01/24/2020	Abbott Prism HCV-Ab Test Date: UNK
1	1a	2,402,964	0.23 (Neg)	NT
2	1b	340400	1.36 (Pos)	NT
3	2b	667309	0.04 (Neg)	NT
4	2b	19051	0.06 (Neg)	NT
5	3a	136404	0.05 (Neg)	NT
6	3a	624016	13.5 (Pos)	NT
7	4	3237248	28.7 (Pos)	NT
8	4	952278	29.5 (Pos)	NT
9	5a	12603	26.0 (Pos)	NT
10	5a	140672	28.5 (Pos)	NT
11	6	7720	35.7 (Pos)	6.45
12	6	Not Detected	34.7 (Pos)	5.54
13	N/A	Not Detected	0.04 (Neg)	NT
14	N/A	Not Detected	0.02 (Neg)	NT

N/A: Not Applicable NT: Not Tested UNK: Unknown

This data is intended to be representative of typical test procedures and should be used for informational purposes only.
They are not intended to represent performance specifications.

REFERENCES:

1. U.S. Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (NIH) 93-8395. Washington: U.S. Government Printing Office, May 1993.
2. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Second Edition, Tentative Guideline. NCCLS Document M29-T2. Villanova, PA: NCCLS, 1991.
3. National Committee for Clinical Laboratory Standards. Clinical Laboratory Waste management; Approved Guideline> NCCLS Document GP 5-A. Villanova, PA: NCCLS, 1993.

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