AcroMetrix™ HCV-S Panel

For research use only. Not for use in diagnostic procedures.

REF 950350 AcroMetrix HCV-S Panel

Product Use
The AcroMetrix™ HCV-S Panel provides a standard across multiple test methods, enabling laboratories and manufacturers to assess molecular procedures (including the RNA extraction step) for the qualitative and quantitative determination of hepatitis C virus (HCV) RNA. For Research Use Only. Not for use in diagnostic procedures.

Summary and Explanation
The AcroMetrix HCV-S Panel members were produced by making quantitative dilutions of SynTura™ HCV, a modified Flaviviridae containing the entire HCV 5' UTR, developed using SynTura Technology™, into normal human plasma (NHP) with EDTA. The NHP was previously tested and found to be non-reactive for HBV DNA, HCV RNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, HBsAg, antibodies to HCV, and antibodies to HTLV I-II.

The AcroMetrix HCV-S Panel was designed and developed to meet the need for highly standardized and controlled nucleic acid testing of HCV. The panel helps to ensure that nucleic acid testing procedures for HCV RNA are properly validated, and test results are consistent across manufacturers, testing laboratories, operators, platforms and assay formats. In order to meet global standardization and harmonization requirements, the panel has been calibrated against the World Health Organization (WHO) International Standard for HCV RNA.

The AcroMetrix HCV-S Panel provides laboratories and manufacturing firms with well-characterized, external quality control samples that allow end users to standardize and compare results obtained by different methodologies, evaluate or compare new molecular test procedures for the detection and/or quantification of HCV RNA, train new operators, and demonstrate assay proficiency.

Principles of the Procedure
The AcroMetrix HCV-S Panel members have been carefully formulated to mimic naturally occurring human samples containing HCV. Additionally, the intact virus format of the AcroMetrix HCV-S Panel Members allows for verification of an effective viral RNA extraction procedure. Therefore, the panel can be used for proficiency and training in any test procedure designed for measuring HCV RNA in human serum or plasma. Because the panel members contain intact viral particles, the test methodology should include an extraction step that releases the viral RNA and makes it available for transcription, amplification and/or hybridization, as appropriate to the test.

Each panel member contains SynTura HCV at a predetermined level calibrated against the WHO International Standard for HCV RNA. Consequently, the assigned values are reported as International Units per milliliter (IU/mL). Some test procedures may report results in units that differ from International Units as defined by WHO.

Reagents

<table>
<thead>
<tr>
<th>AcroMetrix HCV-S Panel Member</th>
<th>HCV Target Concentration (IU/mL)</th>
<th>Volume per Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>AcroMetrix HCV-S 1E2</td>
<td>100</td>
<td>1.2 mL</td>
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<tr>
<td>AcroMetrix HCV-S 5E2</td>
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<tr>
<td>AcroMetrix HCV-S 5E3</td>
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<td>AcroMetrix HCV-S 5E6</td>
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<tr>
<td>AcroMetrix HCV-S 2.5E7</td>
<td>25,000,000</td>
<td>1.2 mL</td>
</tr>
</tbody>
</table>

Precautions and Warning
WARNING: AcroMetrix HCV-S Panel members contain inactivated virus and should be considered biohazardous. Contains ≤0.05% Sodium azide. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials.

Do not pipette by mouth. Use personal protective equipment, including lab coats, gloves and safety glasses.

Do not eat, drink or smoke in areas where panels and specimens are handled.

Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution or equivalent. Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

This product contains 0.05% sodium azide and 0.05% gentamicin sulfate as preservatives. Sodium azide is reported to form potentially explosive metal azides with lead or copper plumbing. Use caution when disposing of these materials and flush drains with sufficient water to prevent buildup of these azides in plumbing systems.

Storage Instructions
The AcroMetrix HCV-S Panel must be stored at -20°C or lower to ensure highest quality. Discard any unused material after use.

Instructions for Use
Thaw the AcroMetrix HCV-S Panel members at room temperature and vortex briefly. In order to reduce possible cloting errors, it is recommended that the panel members be centrifuged for 30 seconds to one (1) minute at ~9000 RCF if an automated extraction method is used.

AcroMetrix HCV-S Panel members should be handled and tested in a manner identical to that required in the HCV RNA test procedure being evaluated. Follow the manufacturer’s or testing laboratory’s instructions and recommendations for the handling and testing of samples.

Representative Data

The data was obtained from customer site evaluations. The performance characteristics of the AcroMetrix HCV-S Panel should be established by each laboratory.

Limitations
For Research Use Only. Not for use in diagnostic procedures.

The AcroMetrix HCV-S Panel cannot be used with assays used to detect HCV bDNA.
References

Glossary:
http://www.thermofisher.com/symbols-glossary