AcroMetrix™ HCV High Control

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IVD **For In Vitro Diagnostic Use**

Rx Only

REF 963003 AcroMetrix HCV High Control

Intended Use
The AcroMetrix™ HCV High Control is intended for use in assessing the performance of nucleic acid test procedures for the determination of hepatitis C virus (HCV) RNA. Routine use of external run controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error. This product is for *in-vitro* diagnostic use.

Composition
The AcroMetrix HCV High Control contains HCV positive plasma diluted in a normal human plasma (NHP) matrix. The NHP was previously tested and found to be negative 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.

Summary and Explanation of the Test
The presence of HCV RNA in human serum or plasma is indicative of active infection, and HCV RNA assays have been added to the armament of diagnostic tools available to clinical testing laboratories worldwide. Commercially available test procedures for determining the presence of HCV RNA in HCV infected individuals contain internal controls for assessing assay validity. However, clinical testing laboratories often require that external (or third party) controls be incorporated into routine testing protocols in order to independently assess assay performance and ensure that test procedures meet established quality control requirements.

The AcroMetrix HCV High Control provides clinical laboratories and diagnostic test manufacturers with quality control samples that have been calibrated to the World Health Organization (WHO) International Standard for HCV RNA for Nucleic Acid Amplification Technology (NAT) Assays (NIBSC Code: 14/150)[1]. The AcroMetrix HCV High Control helps to ensure that nucleic acid testing results for HCV RNA are consistent across manufacturers, testing laboratories, operators, platforms and assay formats.

Principles of the Procedure
The AcroMetrix HCV High Control has been carefully formulated to mimic naturally occurring human specimens containing HCV RNA. Additionally, the intact virus format of the AcroMetrix HCV High Control allows for verification of an effective viral RNA extraction procedure. Therefore, the controls can be used with any test procedure designed for detecting HCV RNA in human serum or plasma. The controls contain encapsidated viral particles, and as such, the test methodology must include an extraction step that releases the viral RNA and makes it available for transcription, amplification and/or detection, as appropriate to the test.

The AcroMetrix HCV High Control is designed to help ensure the quality of nucleic acid test results and to monitor assay performance. Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of these controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error.

Each lot of AcroMetrix HCV High Control is designed to produce a reactive result within a target range established by each testing laboratory. AcroMetrix HCV High Control should be analyzed in the same manner as specimens, according to the appropriate assay Package Insert.

Control Reagents

Catalog Number	HCV RNA Control Name	Quantity	Storage Temperature
963003	AcroMetrix HCV High Control	5 x 1.2 mL	-70°C or lower

⚠ Precautions and Warning
WARNING: The AcroMetrix HCV High Control may contain live intact HCV virus and should be considered potentially infectious and biohazardous. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials[2, 3, 4].

Although the NHP used in the production of these controls was determined to be negative for HBV DNA, HCV RNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, antibodies to HTLV I-II, HBsAg, and antibodies to HCV, all controls should be handled as if capable of transmitting infectious agents.

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 controls and specimens are handled.

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 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.

Operators should be trained on the appropriate use of both the assay and this product prior to use.

Avoid microbial and nuclease contamination of AcroMetrix HCV High Control; use of filtered disposable pipette tips is required.

Storage Instructions
AcroMetrix HCV High Control should be stored at -70°C or lower to ensure highest quality. The control may be refrozen after first use, thawed and used a second time with minimal loss of activity. Discard any unused material after the second use.

Instructions for Use
Thaw the AcroMetrix HCV High Control at room temperature, vortex briefly, and immediately place on ice after thawing. To minimize degradation of the AcroMetrix HCV High Control, return any unused controls to the recommended storage conditions immediately after use.

The AcroMetrix HCV High Control should be handled and tested in a manner identical to that required for clinical specimens run in the HCV RNA test procedure being evaluated. Follow the manufacturer's instructions and recommendations for the handling and testing of clinical specimens.

This independent set of external controls allows testing laboratories and other end users to compare results obtained by different methodologies, evaluate or compare new nucleic acid test procedures for HCV RNA, and demonstrate assay proficiency and reproducibility within the laboratory environment.

Procedure
Controls should be included with every assay run where the specimens are tested, in accordance with manufacturer's procedures or the laboratory's quality control requirements.

Expected Results
AcroMetrix HCV High Control does not have an assigned value. AcroMetrix HCV High Control is designed to produce a reactive result on qualitative nucleic acid assays. The target concentration described on the Certificate of Analysis for Acrometrix HCV High Control should be used for information only. Expected results utilizing AcroMetrix HCV High Control must be established by the end user for their particular assay.

Limitations
The AcroMetrix HCV High Control is not intended for use as a substitute for the internal controls provided by the internal controls provided by in vitro diagnostic kit manufacturers. AcroMetrix HCV High Control must not be substituted for the mandatory calibrators provided with the assay system being utilized. If the results of testing this control are outside the user-defined range, the test must be invalidated. However, positive results for test specimens must not be invalidated and remain the test result of record. Test must be performed and result must be interpreted according to procedures provided with each individual test kit. AcroMetrix HCV High Control is provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated controls and/or reagents may produce erroneous results. AcroMetrix HCV High Control is for In Vitro Diagnostic Use.

References

1. Saldanha, J., Lelie, N., Heath, A. and the WHO Collaborative Study Group. Establishment of the First International Standard for Nucleic Acid Amplification Technology (NAT) Assays for HCV RNA. Vox Sang 1999; 76:149-158.
2. Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
3. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.
4. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.
5. All data was generated at Azienda ULSS 15 Alta Padovana in Camposampiero, Italy.

Glossary:

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

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