AcroMetrix™ NAC HCV Controls

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

REF 950201 AcroMetrix NAC HCV Low Control
950202 AcroMetrix NAC HCV Mid Control

Product Use

The AcroMetrix™ NAC HCV controls are intended for use in assessing the performance of nucleic acid test procedures for the quantitative and qualitative determination of hepatitis C viral RNA (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. The AcroMetrix NAC HCV controls are not intended for use with assays used to screen the blood supply. For Research Use Only. Not for use in diagnostic procedures.

Summary and Explanation

The presence of HCV 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 NAC HCV controls provide clinical laboratories and diagnostic test manufacturers with inactivated quality control samples that have been calibrated to the World Health Organization (WHO) International Standard for Hepatitis C Virus (HCV) RNA for Nucleic Acid Amplification Technology (NAT) Assays[1]. 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.

Principles of the Procedure

The AcroMetrix NAC HCV controls have been carefully formulated to mimic naturally occurring human specimens containing HCV RNA. Therefore, the controls can be used with any test procedure designed for detecting HCV RNA in human serum or plasma.

The AcroMetrix NAC HCV controls are 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.

The low positive control and mid positive control are designed to produce reactive results in HCV RNA assays with sensitivities of at least 200 IU/mL and 5,000 IU/mL, respectively. The controls are for Research Use Only and DO NOT HAVE ASSIGNED VALUES.

Reagents

Catalog Number	Control Name	Number of Vials	Quantity (mL/vial)
950201	AcroMetrix NAC HCV Low Control	5	1.0
950202	AcroMetrix NAC HCV Mid Control	5	1.0

The AcroMetrix NAC HCV controls contain inactivated HCV positive plasma diluted in defibrinated, delipidized normal human plasma (NHP). The NHP was previously tested and found to be negative for HCV RNA, HBV DNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, HBsAg, antibodies to HCV, and antibodies to HTLV I-II. Each control contains 0.05% sodium azide and 0.05% gentamicin sulfate as preservatives.

⚠ Precautions and Warning

WARNING: Although the AcroMetrix NAC HCV controls contain inactivated HCV positive plasma, they should be considered potentially biohazardous. Contains ≤0.05% Sodium azide. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials[2, 3, 4].

Although the defibrinated, delipidized NHP used in the production of these controls was determined to be negative for HCV RNA, HBV DNA, HIV-1 RNA, antibodies to HIV-1 and HIV-2, antibodies to HTLV I-II, HBsAg, and antibodies to HCV, all panel members 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 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 as a preservative. 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

It is recommended that the AcroMetrix NAC HCV controls be stored at -20°C or lower to ensure highest quality. Controls 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. Any controls that appear cloudy or contain precipitates after thawing should be discarded.

Instructions for Use

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

The AcroMetrix NAC HCV controls 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.

Limitations

The AcroMetrix NAC HCV controls are intended for Research Use Only. Not for diagnostic use. They are not intended for use with assays used to screen the blood supply. The AcroMetrix NAC HCV controls DO NOT HAVE ASSIGNED VALUES.

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.

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