

AcroMetrix™ NAC HIV-1 Low and Mid Controls

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

REF 950415 AcroMetrix HIV-1 Low Control
950416 AcroMetrix HIV-1 Mid Control

Product Use

The AcroMetrix™ NAC HIV-1 RNA controls are intended for use in assessing the performance of nucleic acid test procedures for the quantitative and qualitative determination of human immunodeficiency virus type 1 RNA (HIV-1 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 HIV-1 RNA 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 HIV-1 RNA in human serum or plasma is indicative of active infection, and HIV-1 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 HIV-1 RNA in HIV-1 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 HIV-1 RNA controls provide clinical laboratories and diagnostic test manufacturers with an independent set of external controls, which allows testing laboratories and other end users to compare results obtained by different methodologies, evaluate or compare new nucleic acid test procedures for HIV-1 RNA, and demonstrate assay proficiency and reproducibility within the laboratory environment.

Principles of the Procedure

The AcroMetrix NAC HIV-1 RNA controls have been carefully formulated to mimic naturally occurring human specimens containing HIV-1 RNA. Therefore, the controls can be used with any test procedure designed for detecting HIV-1 RNA in human serum or plasma.

The AcroMetrix NAC HIV-1 RNA 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 HIV-1 RNA assays with sensitivities of at least 200 copies/mL and 5,000 copies/mL, respectively. The controls are for *Research Use Only* and DO NOT HAVE ASSIGNED VALUES.

Reagents

Catalog Number	HIV-1 RNA Control Name	Number of Vials	Volume (mL/vial)
950415	AcroMetrix NAC HIV-1 Low Control	5	1.0
950416	AcroMetrix NAC HIV-1 Mid Control	5	1.0

The AcroMetrix NAC HIV-1 RNA controls contain inactivated viral particles derived from molecular infectious clones of HIV-1 propagated in culture. The positive source material has been diluted in normal human plasma (NHP) that 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. Each control contains 0.05% sodium azide and 0.05% gentamicin sulfate as preservatives.

Precautions and Warning

WARNING: Although the AcroMetrix NAC HIV-1 RNA controls contain inactivated HIV-1, 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^{1,2,3}.

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 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 HIV-1 RNA controls be stored at -70°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 HIV-1 RNA controls at room temperature, vortex briefly, and place on ice immediately after thawing. To minimize degradation of HIV-1 RNA, return any unused controls to the recommended storage conditions immediately after use.

The AcroMetrix NAC HIV-1 RNA controls should be handled and tested in a manner identical to that required for clinical specimens run in the HIV-1 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 HIV-1 RNA, and demonstrate assay proficiency and reproducibility within the laboratory environment.

Limitations

For Research Use Only. Not for use in diagnostic procedures. They are not intended for use with assays used to screen the blood supply. The AcroMetrix NAC HIV-1 RNA controls DO NOT HAVE ASSIGNED VALUES.

References

1. Centers for Disease Control (CDC). Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
2. 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.
3. 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.

Glossary:

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



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