AcroMetrix™ Multi-Analyte Control HIV/HCV/HBV Low & High

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 967150 AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low
967151 AcroMetrix Multi-Analyte Control HIV/HCV/HBV High

Intended Use
The AcroMetrix™ Multi-Analyte Control HIV/HCV/HBV Low and High are intended for use in assessing the performance of nucleic acid test procedures for the determination of human immunodeficiency virus (HIV-1) RNA, hepatitis C virus (HCV) RNA and hepatitis B virus (HBV) DNA. 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 Multi-Analyte Control HIV/HCV/HBV Low and High contains one 50mL bottle of Low level or one 50mL of High level, respectively. These materials were produced by diluting inactivated HIV-1 positive plasma, HCV positive plasma, and HBV positive plasma into normal human plasma (NHP). Each bottle contains the following analytes:

- HIV-1
- HCV
- HBV

The normal human plasma (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 HIV RNA or HCV RNA or HBV DNA in human serum or plasma is indicative of active infection, and the assays of HIV RNA, HCV RNA and HBV DNA have been added to the armament of diagnostic tools available to clinical testing laboratories worldwide. Commercially available testing procedures for determining the presence of HIV RNA, HCV RNA and HBV DNA in HIV, HCV and HBV 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 Multi-Analyte Control HIV/HCV/HBV Low and High provides clinical laboratories and diagnostic testing manufacturers with quality control samples that have been calibrated using World Health Organization (WHO) internal standard for HIV-1 RNA (NIBSC Code: 97/650), for HCV (NIBSC Code: 14/150), and for HBV (NIBSC Code: 97/750). The AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High helps to ensure the nucleic acid testing results for HIV RNA, HCV RNA, and HBV DNA are consistent across manufacturers, testing laboratories, operators, platforms and assay formats.

Principles of the Procedure
The AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High has been carefully formulated to mimic naturally occurring human specimens containing HIV RNA, HCV RNA and HBV DNA. Additionally, AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High contains intact, encapsidated viral particles which allows for verification of an effective viral RNA or DNA extraction procedure. Therefore, the test methodology must include an extraction step that releases the viral RNA or DNA, and make it available for transcription, amplification and/or detection, as appropriate to the test.

The AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High is designed to 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, operator variation, and can assist in identifying increases in random or systematic error.

Each lot of AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High is designed to produce a positive result within a target range established by each testing laboratory. AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High should be analyzed in the same manner as specimens according to the appropriate assay package insert.

Control Reagents

Catalog Number	Control Name	Quantity
967150	AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low	1 x 50 mL
967151	AcroMetrix Multi-Analyte Control HIV/HCV/HBV High	1 x 50 mL

⚠ Precautions and Warning
WARNING: Although the AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High contain analytes that are inactive, they should be considered potentially infectious and biohazardous. Contains ≤0.05% Sodium azide. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials[1,2,3].

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 Multi-Analyte Control HIV/HCV/HBV Low and High; use of filtered disposable pipette tips is required.

Storage Instructions
The AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High must be stored at -20°C or below before and after aliquoting to ensure highest quality.

Aliquots may be kept at 2-8°C for a total of 10 days. If aliquots are not to be used within 10 days, freeze aliquots at -20°C or below. When needed, the frozen aliquots may be thawed then stored at 2-8°C for up to 10 days. Do not refreeze aliquots.

Instructions for Use
Thaw the AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High at room temperature, vortex briefly, and aliquot contents entirely within 24 hours into amounts desired for use. Aliquot product into polypropylene screw cap vials (not supplied). Label aliquots with product description including Lot Number and Expiration date.

AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High should be handled and tested in a manner identical to that required for clinical specimen run in the HIV RNA, HCV RNA and HBV DNA testing procedures 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 RNA, HCV RNA, and HBV DNA, 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 Multi-Analyte Control HIV/HCV/HBV Low and High do not have an assigned value. AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High are designed to produce a positive result in quantitative and qualitative nucleic acid assays. The target concentration described on the Certificate of Analysis for AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High should be used for information only. Expected results utilizing AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High must be established by the end user for their particular HIV, HCV and HBV assays.

Limitations

AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High is not intended for use as a substitute for the internal control provided in in vitro diagnostic kit manufacturers. AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High must not be substituted for the mandatory calibrators provided with the assay system to be utilized. If the results of testing AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High 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. Tests must be performed and results interpreted according to procedure provided with each individual testing kit. Deviation from these procedures may produce unreliable results. AcroMetrix Multi-Analyte Control HIV/HCV/HBV Low and High 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 Multi-Analyte Control HIV/HCV/HBV Low and High is for In Vitro Diagnostic Use.

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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