**AcroMetrix™ HIV-1 Low Control**

**Intended Use**
The AcroMetrix™ HIV-1 Low Control is intended for use in assessing the performance of nucleic acid test procedures for the determination of human immunodeficiency virus type 1 (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. This product is for in-vitro diagnostic use.

**Composition**
The AcroMetrix HIV-1 Low Control contains viral particles derived from molecular infectious clones of HIV-1 propagated in culture. This positive source material has been diluted in an EDTA based 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 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 HIV-1 Low Control provides clinical laboratories and diagnostic test manufacturers with inactivated quality control samples that have been calibrated to the World Health Organization (WHO) International Standard for HIV-1 RNA for Nucleic Acid Amplification Technology (NAT) Assays (NISSC Code: 97/650). The AcroMetrix HIV-1 Low Control is designed to produce a reactive result with minimal loss of activity. Discard any unused material after the second use.

**Principles of the Procedure**
The AcroMetrix HIV-1 Low Control has been carefully formulated to mimic naturally occurring human specimens containing HIV-1 RNA. Additionally, the intact virus format of the AcroMetrix HIV-1 Low Control allows for verification of an effective viral RNA extraction procedure. Therefore, the controls can be used with any test procedure designed for detecting HIV-1 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 HIV-1 Low 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.

Each lot of AcroMetrix HIV-1 Low Control is designed to produce a reactive result within a target range established by each testing laboratory. AcroMetrix HIV-1 Low Control should be analyzed in the same manner as specimens, according to the appropriate assay Package Insert.

**Reagents**

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>HIV-1 RNA Control Name</th>
<th>Quantity</th>
<th>Storage Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>964001</td>
<td>AcroMetrix HIV-1 Low Control</td>
<td>5 x 1.2 mL</td>
<td>-70°C or Lower</td>
</tr>
</tbody>
</table>

**Precautions and Warning**

**WARNING:** Although the AcroMetrix HIV-1 Low Control contains inactivated HIV-1 positive material, it should be considered potentially infectious and biohazardous. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials.

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, 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 nucleic acid contamination of AcroMetrix HIV-1 Low Control; use of filtered disposable pipette tips is required.

**Storage Instructions**

AcroMetrix HIV-1 Low Control should be stored at -70°C or lower to ensure highest quality. The AcroMetrix HIV-1 Low 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 HIV-1 Low Control at room temperature, vortex briefly, and immediately place on ice after thawing. To minimize degradation of the AcroMetrix HIV-1 Low Control, return any unused controls to the recommended storage conditions immediately after use.

The AcroMetrix HIV-1 Low Control 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.

**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 HIV-1 Low Control does not have an assigned value. AcroMetrix HIV-1 Low Control is designed to produce a positive result in quantitative and qualitative nucleic acid assays. The target concentration described on the Certificate of Analysis for AcroMetrix HIV-1 Low Control should be used for information only. Expected results utilizing AcroMetrix HIV-1 Low Control must be established by the end user for their particular HIV-1 assay.

**Limitations**

The AcroMetrix HIV-1 Low 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 HIV-1 Low 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 test result must be interpreted according to procedures provided with each individual test kit. AcroMetrix HIV-1 Low 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 HIV-1 Low Control is for In Vitro Diagnostic Use.
References


5. All data was generated at Azienda ULSS 15 Alta Padovana in Camposampiero, Italy.

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