Explanation of symbols used in SeraCare product labeling

- **Upper limit of temperature**
- **Temperature limitation**
- **Authorized Representative in the European Community**
- **Biological risks**
- **Use By**
- **In Vitro Diagnostic Medical Device**
- **Negative control**
- **Catalogue number**
- **Consult instructions for use**
- **Positive control**
- **Batch code**
- **Manufacturer**
- **Control**
- **Highly Flammable**
- **Toxic by inhalation, in contact with skin and if swallowed**
- **Health Hazard**
NAME AND INTENDED USE
ACCURUN® 2 controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 2 Multi-Marker Positive Controls have been formulated for use with in vitro diagnostic test kits for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1 and 2), antibodies to Human T-Lymphotropic Virus Types I and II (HTLV I and II), antibodies to Hepatitis B Core Antigen (HBcAg), antibodies to Hepatitis C Virus (HCV), antibodies to Cytomegalovirus (CMV), antibodies to Treponema pallidum (Syphilis) and Hepatitis B Surface Antigen (HBsAg). A negative control for these analytes is available separately from SeraCare Life Sciences.

QUALITY CONTROL
Since ACCURUN® 2 controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN® 2 control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS
Levels of reactivity of ACCURUN® 2 Positive Controls may vary with different manufacturers’ tests and different test lot lots. Different series of ACCURUN® 2 controls are formulated to yield different reactivity levels for anti-HIV 1, anti-HIV 2, and other analytes. Each laboratory must establish its own range of acceptable values for ACCURUN® 2 controls with the particular test kits being used. When results for ACCURUN® 2 controls are outside the established acceptable range of values, it may be an indication of unsatisfactory test performance. Possible sources of discrepancy include: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

LIMITATIONS OF THE PROCEDURE
ACCURUN® 2 CONTROLS MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS. TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN® 2 controls are 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 may produce erroneous results.

EXPECTED RESULTS
ACCURUN® 2 CONTROLS DO NOT HAVE ASSIGNED VALUES. This positive control has been formulated to produce positive reactivity in those manufacturers’ assays listed in Table 1. Specific levels of reactivity will vary among different manufacturers’ assays, different procedures, different lot numbers, and different laboratories.

REAGENTS
ACCURUN® 2 controls have been designed for use in vitro assay procedures for purposes of monitoring test performance. ACCURUN® 2 Positive Controls are manufactured from human serum or plasma, including materials reactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, HBeAg, HBeAg, HCV, CMV and Treponema pallidum. ACCURUN® 2 controls do not have assigned values. This positive control was not formulated to produce positive reactivity in those manufacturers’ assays listed in Table 1. Specific levels of reactivity will vary among different manufacturers’ assays, different procedures, different lot numbers, and different laboratories.

SAFETY PRECAUTIONS
Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN® 2 controls and human blood products as though capable of transmitting infectious agents. ACCURUN® 2 Positive Controls are manufactured from human serum or plasma, including materials reactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, HBeAg, HCV, CMV and Treponema pallidum.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
Alterations in physical appearance may indicate instability or deterioration of ACCURUN® 2 controls. Solutions that are visibly turbid should be discarded.

PROCEDURE
MIX THE CONTENTS OF THE VIALS BY GENTLY SWIRLING. ALLOW THE CONTROLS TO REACH ROOM TEMPERATURE BEFORE USE, THEN RETURN CONTROLS TO REFRIGERATED STORAGE IMMEDIATELY AFTER USE. ACCURUN® 2 controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN® 2 controls must NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH LICENSED TEST KITS.

For assistance, contact SeraCare Technical Support at +1.508.244.6400.

Table 1. ACCURUN® 2 Series 2700 has been formulated to produce positive reactivity in the following manufacturers’ assays.

<table>
<thead>
<tr>
<th>Marker</th>
<th>Manufacturer/Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV 1/2</td>
<td>Abbott ARCHITECT® HIV Ag/Ab Combo</td>
</tr>
<tr>
<td>Anti-HTLV III</td>
<td>Abbott ARCHITECT® HTLV-III</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>Abbott ARCHITECT® HCV</td>
</tr>
<tr>
<td>HBeAg</td>
<td>Abbott ARCHITECT® HBsAg Qualitative</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Abbott ARCHITECT® CORE</td>
</tr>
<tr>
<td>Anti-CMV</td>
<td>Abbott ARCHITECT® CMV IgG</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Abbott ARCHITECT® Syphilis TP</td>
</tr>
</tbody>
</table>

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