Explanation of symbols used in SeraCare product labeling

- Upper limit of temperature
- Temperature limitation
- Biological risks
- Use By
- Authorized Representative in the European Community
- In Vitro Diagnostic Medical Device
- Consult instructions for use
- Manufacturer
- Toxic by inhalation, in contact with skin and if swallowed
- Highly Flammable
- Control
- Negative control
- Positive control
- Catalogue number
- Batch code
- Health Hazard
**ACCURUN® 1 SERIES 4400 Multi-Marker Positive Control**

**NAME AND INTENDED USE**
ACCURUN 1 controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 1 Multi-Marker Positive Controls are 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 (HBsAg), antibodies to Hepatitis C Virus (HCV), antibodies to Cytomegalovirus (CMV), and Hepatitis B Surface Antigen (HBsAg). A negative control for these analytes is available separately from SeraCare Life Sciences.

**SUMMARY**
Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of 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. A well designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of low-reactive samples as independent controls may provide valuable information concerning laboratory proficiency and lot variation that may affect assay sensitivity.

**PRINCIPLES OF THE PROCEDURE**
ACCURUN 1 controls are designed for use with in vitro assay procedures for purposes of monitoring assay performance. ACCURUN 1 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, HBsAg, HCV, and CMV. ACCURUN 1 controls do not have assigned values. This control is formulated to produce positive reactivity with the test kits listed in Table 1. Specific levels of reactivity will vary among different manufacturers’ assays, different procedures, different lot numbers, and different laboratories.

**REAGENTS**
Item No. 2000-0010 12 vials, 3.5 ml per vial

This control contains stabilizers (EDTA, buffering agents) and 0.1% ProClnR (5-chloro-2-methyl-4-isothiazol-3-one & 2-methyl-4-isothiazolin-3-one) as preservative. Reactive materials have been treated with beta-propiolactone and ultraviolet irradiation.

**WARNINGS AND PRECAUTIONS**
**For In Vitro Diagnostic Use.**

**CAUTION:** Handle ACCURUN 1 controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 1 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, HBsAg, HCV, and CMV. Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN 1 controls and human blood. Do not pipette by mouth; do not eat or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens, controls and materials used in testing as though they contain infectious agents.

**Handling Precautions**
Do not use ACCURUN 1 controls beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

**STORAGE INSTRUCTIONS**
Store ACCURUN 1 controls refrigerated at 2-8°C. Once opened, ACCURUN 1 controls should be stored at 2-8°C and discarded after 60 days. After opening, record the date opened and the expiration date on the vial. Multiple freeze-thaw cycles are not recommended, and may have variable adverse effects upon test results. To prevent leakage, store vials upright.

**INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION**
Alterations in physical appearance may indicate instability or deterioration of ACCURUN 1 controls. Solutions that are visibly turbid should be discarded.

**PROCEDURE**
**Materials Provided**
ACCURUN 1 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, HBsAg, HCV, and CMV. See REAGENTS for a list of package sizes. A negative control for these analytes is also available separately from SeraCare Life Sciences.

**Materials Required but not Provided**
Refer to instructions supplied by manufacturers of the test kits to be used.

**Instructions for Use**
Mix the contents of the vials by gently swirling. Allow the controls to reach room temperature prior to use, then return controls to refrigerated storage immediately after use. ACCURUN 1 controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN 1 controls must NOT be substituted for the positive and negative control reagents provided with licensed test kits.

**Quality Control**
Since ACCURUN 1 controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN 1 control with each specific assay system prior to its routine use in the laboratory.

**INTERPRETATION OF RESULTS**
Levels of reactivity of ACCURUN 1 Positive Controls may vary with different manufacturers’ tests and different test kits. Different series of ACCURUN 1 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 1 controls with the particular test kits being used. When results for ACCURUN 1 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 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. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN 1 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 1 CONTROLS DO NOT HAVE ASSIGNED VALUES. This control is formulated to produce positive reactivity with the test kits listed in Table 1. Specific levels of reactivity will vary among different manufacturers’ assays, different procedures, different reagent lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values for each analyte. For example, the acceptable range might include all values within 2 standard deviations of the mean of 20 data points obtained in 20 runs over a period of 30 days.

**SPECIFIC PERFORMANCE CHARACTERISTICS**
ACCURUN 1 controls are designed for use with in vitro assay procedures for purposes of monitoring assay performance. ACCURUN 1 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, HBsAg, HCV, and CMV. ACCURUN 1 controls do not have assigned values. This control is formulated to produce positive reactivity with the test kits listed in Table 1. Specific levels of reactivity will vary among different manufacturers’ assays, different procedures, different reagent lot numbers, and different laboratories. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

**REFERENCES**

Table 1. ACCURUN 1 Series 4400 is formulated to produce positive reactivity with the following test kits.

<table>
<thead>
<tr>
<th>Markers</th>
<th>Manufacturer</th>
<th>Product Name</th>
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<tbody>
<tr>
<td>anti-HIV 1/2</td>
<td>Bio-Rad Laboratories</td>
<td>Genetic Systems HIV-1/HIV-2 Plus O EIA</td>
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<tr>
<td>anti-HTLV III</td>
<td>Avio Inc.</td>
<td>Avio Avio HTLV-III Microelisa System</td>
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<tr>
<td>HBsAg</td>
<td>Bio-Rad Laboratories</td>
<td>Genetic Systems HBsAg EIA 3.0</td>
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<td>anti-HBV</td>
<td>Ortho-Clinical Diagnostics</td>
<td>Ortho HBs ELISA Test System</td>
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<tr>
<td>anti-HCV</td>
<td>Ortho-Clinical Diagnostics</td>
<td>Ortho HCV Version 3.0 ELISA Test System</td>
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For assistance, contact SeraCare Technical Support at +1 508.244.6400.