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**
**ACCURUN® 1 Multi-Marker Negative Control**

**NAME AND INTENDED USE**

ACCURUN® 1 Multi-Marker Negative Control is intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN 1 Multi-Marker Negative Control is formulated for use with in vitro diagnostic test kits for the detection of Hepatitis B Surface Antigen (HBsAg), Human Immunodeficiency Virus Type 1 Antigen (HIV-1 Ag) and antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and 2), antibodies to Hepatitis B Core Antigen (HbcAg), antibodies to Hepatitis C Virus (HCV), antibodies to Cytomegalovirus (CMV), and antibodies to Treponema pallidum (Syphilis). Positive controls for these analytes are available separately from SeraCare Life Sciences.

**Materials Provided**

ACCURUN 1 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg and HIV-1 Ag, and antibodies to HIV 1 and 2, HTLV I and II, HbcAg, HCV, CMV and Treponema pallidum. ACCURUN 1 Multi-Marker Negative Control is formulated to be nonreactive in the 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 1 controls and human blood. Don’t pipette by mouth; do not eat or drink in areas where specimens are being handled. Clean any spills immediately using 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 Multi-Marker 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 discarded after 60 days. After opening, record 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 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg and HIV-1 Ag, and antibodies to HIV 1 and 2, HTLV I and II, HbcAg, HCV, CMV and Treponema pallidum. See REAGENTS for a list of package sizes. Positive controls for these analytes are also available from SeraCare Life Sciences.

**Materials Required but not Provided**

Refers to instructions supplied by manufacturers of the test kits to be used.

**Instructions for Use**

Mix the contents of the vials by gentle inversion. Allow the control to reach room temperature prior to use, then return to refrigerated storage immediately after use. ACCURUN 1 Multi-Marker Negative Control should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN 1 Multi-Marker Negative Control must NOT be substituted for the negative control reagent provided with licensed test kits.

**Quality Control**

Since ACCURUN 1 Multi-Marker Negative Control does not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN 1 Multi-Marker Negative Control with each specific assay system prior to its routine use in the laboratory.

**INTERPRETATION OF RESULTS**

Levels of reactivity of ACCURUN 1 Multi-Marker Negative Control may vary with different manufacturers’ tests and different test kit lots. 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 1 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 1 controls are provided for quality assurance purposes and must not be used for calibration or as 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 MULTI-MARKER NEGATIVE CONTROL DOES NOT HAVE ASSIGNED VALUES.

The negative control is formulated to be nonreactive in those manufacturers’ assays 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 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg and HIV-1 Ag, and antibodies to HIV 1 and 2, HTLV I and II, HbcAg, HCV, CMV and Treponema pallidum. ACCURUN 1 Multi-Marker Negative Control does not have assigned values. The negative control is formulated to be nonreactive in those manufacturers’ assays 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 Multi-Marker Negative Control is formulated to be nonreactive in the following manufacturers’ assays:**

<table>
<thead>
<tr>
<th>Marker</th>
<th>Manufacturer/Product Name</th>
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<tbody>
<tr>
<td>HIV-1/2</td>
<td>Bio-Rad GS HIV-1/2 p24 O EIA</td>
</tr>
<tr>
<td>HIV 2</td>
<td>Genetic Systems® HIV 2 EIA</td>
</tr>
<tr>
<td>HIV-1 Ag</td>
<td>PerkinElmer HIV-1 p24 ELISA</td>
</tr>
<tr>
<td>HTLV-III</td>
<td>Abbott PRISM HTLV-III</td>
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<tr>
<td>HCV</td>
<td>Ortho® HCV 3.0 ELISA Test System</td>
</tr>
<tr>
<td>HbsAg</td>
<td>DiaSorin E1k-MAK-2 Plus HbsAg EIA</td>
</tr>
<tr>
<td>HbsAg</td>
<td>Genetic Systems® HBsAg EIA (proc. A)</td>
</tr>
<tr>
<td>Hbc</td>
<td>Ortho® Hbc ELISA Test System</td>
</tr>
<tr>
<td>CMV</td>
<td>Trinity Biotech Capita® CMV IgG ELISA</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Trinity Biotech Capita® Seraphine-G EIA</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Olympus PK™</td>
</tr>
</tbody>
</table>

For assistance, contact SeraCare Technical Support at +1 508.244.6400.