Explanation of symbols used in SeraCare product labeling

- **Upper limit of temperature**: Indicates the maximum temperature allowed for the product.
- **Temperature limitation**: Indicates the temperature range within which the product should be stored or used.
- ** Biological risks**: Indicates potential hazards related to biological substances.
- **Use By**: Indicates the expiration date of the product.
- **In Vitro Diagnostic Medical Device (IVD)**: Indicates that the product is a diagnostic device used in vitro.
- **Consult instructions for use**: Indicates that the user should refer to the product's instructions for use.
- **Manufacturer**: Indicates the company that manufactured the product.
- **Toxic by inhalation, in contact with skin and if swallowed**: Indicates potential hazards related to ingestion or inhalation.
- **Control**: Indicates the control status of the product.
- **Catalogue number**: Indicates the unique identifier for the product.
- **Batch code**: Indicates the batch number associated with the product.

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10005US-20 February 2017
**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) and Antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV 1 and 2), Antibodies to Human T-Lymphotropic Virus Types 1 and II (HTLV I and II), 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. For In Vitro Diagnostic Use.

**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 specific quality assurance 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 is nonreactive in the following 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>HIV1/2</td>
<td>Bio-Rad GS HIV-1/HIV-2 Plus O EIA</td>
</tr>
<tr>
<td>HIV-2</td>
<td>Genetic Systems® HIV 2 EIA</td>
</tr>
<tr>
<td>HIV-1 p24</td>
<td>PerkinElmer HIV-1 p24 ELISA</td>
</tr>
<tr>
<td>HTLV-III</td>
<td>Abbott PRISM HTLV-1/HTLV-2</td>
</tr>
<tr>
<td>HCV</td>
<td>Ortho® HCV HCV 3.0 ELISA Test System</td>
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<tr>
<td>HBsAg</td>
<td>DiaSorin EIT-MAK-2 Plus HBsAg EIA</td>
</tr>
<tr>
<td>HbcAg</td>
<td>Genentech Systems® HBc Ag EIA (pro A)</td>
</tr>
<tr>
<td>CMV</td>
<td>Ortho® Hbc ELISA Test System</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Trinity Biotech Captia™ CMV lgG ELISA</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Trinity Biotech Captia™ Syphilis-G EIA</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Olympus PK™ 720</td>
</tr>
</tbody>
</table>

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