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® 810 Multi-Marker Negative Control**

**NAME AND INTENDED USE**
ACCURUN® controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 810 Multi-Marker Negative Control has been formulated for use with in vitro diagnostic test kits for the qualitative determination of Hepatitis B Surface Antigen (HBsAg), Hepatitis B e Antigen (HBeAg), Syphilis RPR, and antibodies to Hepatitis B Surface Antigen (HBs), Hepatitis B Core Antigen (HBc) and HBeAg, Hepatitis B e Antigen (HBe), Hepatitis C Virus (HCV), Hepatitis A Virus (HAV and HAV IgM), Cytomegalovirus (CMV), Treponema pallidum (Syphilis ATA), Borrelia burgdorferi (Lyme IgG and Lyme IgM), HIV 1 and 2, and HTLV I and II. Positive controls for many of these analytes are available separately from SeraCare Life Sciences. For In Vitro Diagnostic Use.

**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 independent controls may provide valuable information concerning laboratory proficiency and lot-to-lot variation that may affect assay sensitivity.

**PRINCIPLES OF THE PROCEDURE**
ACCURUN 810 Multi-Marker Negative Control is designed for use with in vitro assay procedures for purposes of monitoring test performance. ACCURUN 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, HBeAg, anti-HBs, anti-HBe, anti-HBc Igm, anti-HBc, anti-HCV, anti-HAV IgM, anti-HAV IgG, CMV, and Syphilis RPR. Antibodies to HBs, HBc, HBe, HCV, HAV, HAV IgM, HIV 1 and 2, HTLV I and II, Lyme IgG and Lyme IgM, Syphilis ATA. ACCURUN controls do not have assigned values. This control has been formulated to produce negative 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**
Item No. 20.10-0020 6 vials, 3.5 ml per vial

This control contains stabilizers (EDTA, buffering agents), and 0.1% ProClin® (5-chloro-2-methyl-4-isothiazolin-3-one & 2-methyl-4-isothiazolin-3-one) as preservative.

**WARNINGS AND PRECAUTIONS**

**CAUTION:** Handle ACCURUN controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, and antibodies to HIV 1 and 2, HTLV I and II and HCV with current FDA licensed tests.

**Safety Precautions**
Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN 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 controls beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

**STORAGE INSTRUCTIONS**
Store ACCURUN 810 Multi-Marker Negative Control at 2-8°C. Once opened, ACCURUN 810 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 on 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 controls. Solutions that are visibly turbid should be discarded.

**PROCEDURE**

**Materials Provided**
ACCURUN 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, HBeAg, Syphilis RPR and antibodies to HBs, HBe, HBc IgM, CMV, HBe, HCV, HAV, HAV IgM, HIV 1 and 2, HTLV I and II, Lyme IgG and IgM, and Syphilis ATA.

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

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

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

**INTERPRETATION OF RESULTS**
Levels of reactivity of ACCURUN 810 Multi-Marker Negative Control may vary with different manufacturers’ tests and different test kits. Since the control does not have an assigned value, the laboratory must establish a range for each lot of ACCURUN 810 Multi-Marker Negative Control. When results for ACCURUN 810 Multi-Marker Negative Control 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 closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN controls are not calibrators and should not be used for assay calibration. Performance characteristics for ACCURUN 810 Multi-Marker Negative Control have been established only for HBsAg, HBeAg, anti-HBs, anti-HBe, anti-HBc IgM, anti-HBc, anti-HCV, anti-HIV, anti-HAV-IgM, anti-HIV 1 and 2, Lyme IgG, Lyme IgM, anti-HTLV-I and II anti-CMV, Syphilis ATA and Syphilis RPR. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

**EXPECTED RESULTS**
ACCURUN 810 Multi-Marker Negative Control DOES NOT HAVE AN ASSIGNED VALUE.

This control has been formulated to produce negative 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. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory. 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 controls are designed for use with in vitro assay procedures for purposes of monitoring assay performance. ACCURUN 810 Multi-Marker Negative Control is manufactured from human serum or plasma nonreactive for HBsAg, HBeAg, Syphilis RPR and antibodies to HBs, HBe, HBc IgM, CMV, HBe, HCV, HAV, HAV IgM, HIV 1 and 2, HTLV I and II, Lyme IgG and IgM, and Syphilis ATA. ACCURUN controls do not have assigned values. This negative control is formulated to produce negative reactivity in those manufacturers’ assays listed in Table 1. Specific levels of reactivity vary among different manufacturers’ assays, different procedures, different 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 810 Multi-Marker Negative Control is nonreactive in the following manufacturers’ tests:**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Manufacturer</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>DiaSorin, Stillwater MN</td>
<td>ETI-MAX 2 PLUS EIA</td>
</tr>
<tr>
<td>HBeAg</td>
<td>Bio-Rad Laboratories, Redmond, WA</td>
<td>Genetic Systems HBsAg EIA 3.0, proc. B</td>
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<td>anti-CMV</td>
<td>Trinity Biotech, Brackley, Ireland</td>
<td>CAPTIA CMV</td>
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<tr>
<td>anti-HBC</td>
<td>DiaSorin, Stillwater MN</td>
<td>ETI-AB-CORE PLUS</td>
</tr>
<tr>
<td>anti-HBc</td>
<td>Ortho Diagnostics, Raritan, NJ</td>
<td>Hbc ELISA</td>
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<tr>
<td>anti-HBcIgM</td>
<td>Abbott Laboratories, Abbott Park, IL</td>
<td>Abbott ARCHITECT® CORE-M™</td>
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<tr>
<td>anti-HBc</td>
<td>DiaSorin, Stillwater MN</td>
<td>ETI-AB-AUK PLUS</td>
</tr>
<tr>
<td>anti-HBe</td>
<td>DiaSorin, Stillwater MN</td>
<td>ETI-AB-EBK PLUS (anti-HbE)</td>
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<td>anti-HV IgM</td>
<td>DiaSorin, Stillwater MN</td>
<td>ETI-AB-EBK PLUS EIA (HBsAg)</td>
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<tr>
<td>anti-HCV</td>
<td>Ortho Diagnostics, Raritan, NJ</td>
<td>HCV 3.0 ELISA</td>
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<tr>
<td>anti-HIV</td>
<td>DiaSorin, Stillwater MN</td>
<td>ETI-AB-HAIGM PLUS</td>
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<td>anti-HIV I/2</td>
<td>Bio-Rad Laboratories, Redmond, WA</td>
<td>Genetic Systems HIV-1/2</td>
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<td>anti-HIV II</td>
<td>Bio-Rad Laboratories, Redmond, WA</td>
<td>Genetic Systems HIV-2 EIA</td>
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<td>anti-HTLV III</td>
<td>Abbott Laboratories, Abbott Park, IL</td>
<td>PRISM HTLV-HTLVIII</td>
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<td>Lyme IgG</td>
<td>Zeus Scientific Inc., Branchburg, NJ</td>
<td>Wampole B. burgdorferi IgG ELISA II</td>
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<tr>
<td>Lyme IgM</td>
<td>Zeus Scientific Inc., Branchburg, NJ</td>
<td>Wampole B. burgdorferi IgM ELISA II</td>
</tr>
<tr>
<td>Syphilis ATA</td>
<td>Trinity Biotech plc, Dublin, Ireland</td>
<td>Capilia Syphilis G EIA</td>
</tr>
</tbody>
</table>

For assistance, contact SeraCare Technical Support at +1.508.244.8400.