About this package insert

Thank you for your interest in this ACCURUN product. This package insert consists of two pages. The first page contains the product name and an explanation of the symbols used on the labeling. The second page contains the complete package insert text.

If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at info@seracare.com. By phone: US customers call 800.676.1881; International customers call collect 508.634.3359.

A printed package insert will be sent to you upon request.

Explanation of symbols used in SeraCare product labeling

- Harmful/Irritant
  - This product contains 0.1% ProClin® 300.
  - R43 May cause sensitization by skin contact.
  - S24 Avoid contact with skin.
  - S35 This material and its container must be disposed of in a safe way.
  - S37 Wear suitable gloves.

- Upper limit of temperature
- Temperature limitation

- Biological risks
- Use By

- "Caution, consult accompanying documents"

- CONTROL - Negative control
- REF Catalogue number
- IVD In Vitro Diagnostic Medical Device

- CONTROL + Positive control
- LOT Batch code

SeraCare Life Sciences, Inc. | 25 Birch Street, Milford, MA 01757 USA
Phone: 508.244.6400 | info@seracare.com

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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 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), 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 kit 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, HBcAg, 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
Cat. No. A001-4408-P 12 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. 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, HBcAg, HCV, and CMV. 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. 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, HBcAg, HCV, and CMV. ACCURUN 1 controls do not have assigned values. This control is formulated to produce positive reactive 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.

REFERENCES

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

<table>
<thead>
<tr>
<th>Marker</th>
<th>Manufacturer</th>
<th>Product Name</th>
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</thead>
<tbody>
<tr>
<td>HIV 1/2</td>
<td>Bio-Rad Laboratories</td>
<td>Genetic Systems HIV-1/HIV-2 Plus O EIA</td>
</tr>
<tr>
<td>HIV 1/2</td>
<td>Avon Inc.</td>
<td>Avon HIV-1/2 Microlatex System</td>
</tr>
<tr>
<td>HBsAg</td>
<td>Bio-Rad Laboratories</td>
<td>Genetic Systems HBsAg EI/A</td>
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<tr>
<td>HIV 1/2</td>
<td>Ortho-Clinical Diagnostics</td>
<td>Ortho HCV ELISA Test System</td>
</tr>
<tr>
<td>HBsAg</td>
<td>Ortho-Clinical Diagnostics</td>
<td>Ortho HCV Version 3.0 ELISA Test System</td>
</tr>
<tr>
<td>CMV</td>
<td>Trinity Biotech USA</td>
<td>Capita CMV IgG</td>
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</tbody>
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For assistance, contact SeraCare Technical Support at 508.244.6400.