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 antibodies) and 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.

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-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 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 test 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 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.

REAGENTS
Item No. 2010-0013 1 vial, 5.0 mL per vial
Item No. 2010-0015 12 vials, 3.5 mL per vial

This negative control contains stabilizers (EDTA, buffering agents) and 0.1% ProClin L30 (5-chloro-2-methyl-4-isothiazolin-3-one & 2-methyl-4-isothiazolin-3-one) as preservative.

SAFETY PRECAUTIONS
For In Vitro Diagnostic Use
CAUTION: Handle ACCURUN 1 Multi-Marker Negative Control and all human blood products as though capable of transmitting infectious agents. ACCURUN 1 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, HCV, and current FDA licensed tests.

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.

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