Explanation of symbols used in SeraCare product labeling

- **Upper limit of temperature**
- **Temperature limitation**
- **Biological risks**
- **Use By**
- **Authorized Representative in the European Community**
- **In Vitro Diagnostic Medical Device**
- **Catalogue number**
- **Consult instructions for use**
- **Manufacturer**
- **Batch code**
- **Highly Flammable**
- **Toxic by inhalation, in contact with skin and if swallowed**
- **Control**
- **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 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 HBc IgM), Hepatitis B e Antigen (HBe), Hepatitis C Virus (HCV), Hepatitis A Virus (HAV and HAV IgM), Cytoomegalovirus (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 performance and kit 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, anti-HAV IgM, anti-CMV and Syphilis RPR, and antibodies to HIV 1 and 2, HTLV I and II, Lyme IgG and Lyme IgM, Syphilis ATA, ACCURUN controls do not have assigned values. Specific levels of reactivity will vary among different manufacturers’ assays, different procedures, different lot numbers, and different laboratories.

**REAGENT INSTABILITY OR DETERIORATION**
For In Vitro Diagnostic Use.

**SAFETY PRECAUTIONS**
Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and 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.

**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, Hbc, 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.