

Multi-Marker Negative Control

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.



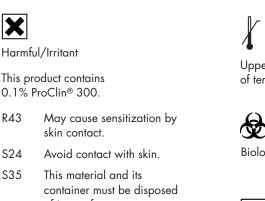
MEDIMARK® Europe 11, rue Émile Zola BP 2332 38033 Grenoble Cedex 2 – France + 33 (0) 4 76 86 43 22 info@medimark-europe.com



SeraCare Life Sciences, Inc. 25 Birch Street, Milford, MA 01757 USA Phone: 001.508.244.6400 info@seracare.com

July 2013 12665US-01

Explanation of symbols used in SeraCare product labeling



- of in a safe way.
- S37 Wear suitable gloves.

Upper limit of temperature

Biological risks



Negative control

CONTROL +

Positive control



Catalogue number

Temperature

limitation

Use By

LOT



"Caution, consult accompanying documents"

EC REP

Authorized Representative in the European Community

IVD

In Vitro Diagnostic Medical Device



Batch code



ACCURUN[®] 810

Multi-Marker Negative Control

THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

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 (HBs), Hepatitis B Core Antigen (HBc), Nepatitis B e Antigen (HBc), Hepatitis B Core Antigen (HBc), Ortomegalovirus (CMV), *Treponema pallidum* (Syphilis ATA), *Barrelia 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 kit lot variation that may affect assay sensitivity¹.

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, HBsAg, nHB-HBs, anti-HBs, 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.

REAGENTS

Cat. No. A810-0001 1 vial, 5.0 mL per vial Cat. No. A810-0005 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

For In Vitro Diagnostic Use.

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 blood². 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 viai. Multiple freeze-thaw cycles are not recommended, and may have variable adverse effects on test results. To prevent leakage, store viais 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.

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 kit lots. 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-HBc IgM, anti-HBe, anti-HCV, anti-HAV, 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. 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 days³.

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 huma 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 1 and II, Lyme IgG and IgM, and 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. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

REFERENCES

- Green IV GA, Carey RN, Westgard JO, Carten T, Shablesky LA, Achord D, Page E, and Le AV. Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin. Chem. 43:9 1618–1621, 1997.
- CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp. 2), 1987.
- Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Second Edition. NCCLS document C24-A2, 1999.

For assistance, contact SeraCare Technical Support at 001.508.244.6400.



July 2013 12665US-01