



ACCURUN[®] 1

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.



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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



Biological risks



Negative control



Positive control



Temperature limitation



Use By



Catalogue number



Batch code



"Caution, consult accompanying documents"



Authorized Representative in the European Community



In Vitro Diagnostic Medical Device

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

NAME AND INTENDED USE

Frequent testing of independent quality control samples 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 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 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 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 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

Cat. No. A001-1001-N 1 vial, 5.0 mL per vial
Cat. No. A001-1008-N 12 vials, 3.5 mL per vial

This negative 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 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 and HCV with current FDA licensed tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN 1 controls 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 1 Multi-Marker controls beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

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.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Mix the contents of the vials by gentle inversion. Allow the control to reach room temperature prior to use, then return to refrigerated storage immediately after use. ACCURUN 1 Multi-Marker Negative Control should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN 1 Multi-Marker Negative Control must NOT be substituted for the negative control reagent provided with licensed test kits.

Quality Control

Since ACCURUN 1 Multi-Marker Negative Control does not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN 1 Multi-Marker Negative Control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 1 Multi-Marker Negative Control may vary with different manufacturers' tests and different test kit lots. 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 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 closely. 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 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 MULTI-MARKER NEGATIVE CONTROL DOES NOT HAVE ASSIGNED VALUES. The negative control is formulated to be nonreactive in those manufacturers' assays 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 days³.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN 1 controls are designed for use with *in vitro* assay procedures for purposes of monitoring assay 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 does not have assigned values. The negative control is formulated to be nonreactive in those manufacturers' assays listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent 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.

Table 1. ACCURUN 1 Multi-Marker Negative Control is formulated to be nonreactive in the following manufacturers' assays:

Marker	Manufacturer/Product Name
HIV1/2	Bio-Rad GS HIV-1/HIV-2 Plus O EIA
HIV 2	Genetic Systems® HIV 2 EIA
HIV-1 Ag	PerkinElmer HIV-1 p24 ELISA
HTLV I/II	Abbott PRISM HTLV-I/HTLV-II
HCV	Ortho® HCV 3.0 ELISA Test System
HBsAg	DiaSorin ETI-MAK-2 Plus HBsAg EIA
HBsAg	Genetic Systems HBsAg EIA (proc. A)
HBc	Ortho® HBc ELISA Test System
CMV	Trinity Biotech Captia™ CMV IgG ELISA
Syphilis	Trinity Biotech Captia™ Syphilis-G EIA
Syphilis	Olympus PK™ 7200

For assistance, contact SeraCare Technical Support at 001.508.244.6400.