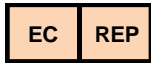


ACCURUN® 40 SERIES 5000

Anti-Measles, Mumps, Rubella, VZV Positive Control



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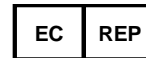
Explanation of symbols used in SeraCare product labeling



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® 40 SERIES 5000 Anti-Measles, Mumps, Rubella, VZV Positive 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® 40 Anti-Measles, Mumps, Rubella, VZV Positive Control Series 5000 is formulated for use with in vitro diagnostic test kits for the qualitative determination of IgG antibodies to Measles, Mumps, Rubella, and Varicella Zoster (VZV).
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 low-reactive samples as independent controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity¹.

PRINCIPLES OF THE PROCEDURE

ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control is designed for use with in vitro assay procedures for purposes of monitoring test performance. ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control is manufactured from human plasma reactive for IgG antibodies to Measles, Mumps, Rubella, and VZV and nonreactive for HBsAg and for antibodies to HIV 1 and 2, HTLV I and II, and HCV. 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

Item No. 2000-0039 3 vials, 1.0 ml per vial

This control contains EDTA and buffering agents as stabilizers, 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 40 Anti-Measles, Mumps, Rubella, VZV Positive Control is manufactured from human 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 40 Anti-Measles, Mumps, Rubella, VZV Positive Control at 2-8°C. Once opened, ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control 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 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 controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control is manufactured from human plasma reactive for IgG antibodies to Measles, Mumps, Rubella, and VZV and nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV.

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 40 Anti-Measles, Mumps, Rubella, VZV Positive Control may vary with different manufacturers' tests and different test kit lots. Each laboratory must establish its own range of acceptable values for ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control with the particular test kits being used. When results for ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control are outside the established acceptable range of values, it may be an indication of unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment and 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 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 40 Anti-Measles, Mumps, Rubella, VZV Positive Control DOES NOT HAVE AN ASSIGNED VALUE. 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 controls are designed for use with in vitro assay procedures for purposes of monitoring assay performance. ACCURUN 40 Anti-Measles, Mumps, Rubella, VZV Positive Control is manufactured from human plasma reactive for IgG antibodies to Measles, Mumps, Rubella, VZV, and nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV. ACCURUN controls do not have assigned values. 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
- Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
- 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 +1.508.244.6400.