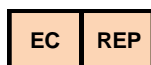


ACCURUN® 803

Nucleic Acid Negative
Quality Control (HIV, HCV, HBV)



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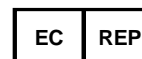
Explanation of symbols used in SeraCare product labeling



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® 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV)

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® 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is formulated for use with *in vitro* diagnostic test procedures that detect HIV-1 RNA, HCV RNA and HBV DNA.

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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is manufactured from human serum or plasma negative for HIV-1 RNA, HCV RNA and HBV DNA, and nonreactive for HBsAg and antibodies to HIV 1 and 2, HCV and HTLV. ACCURUN controls do not have assigned values. This control is formulated to produce negative reactivity with the test kits listed in Table 1. Levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers and different laboratories.

REAGENTS

Item No. 2035-0007 10 vials, 1.2 ml per vial

ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) contains stabilizers (EDTA, buffering agents) and 0.09% sodium azide 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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HCV and HTLV with current FDA licensed tests.

SAFETY PRECAUTIONS

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and patient samples². Do not pipette by mouth; do not smoke, 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 contamination of the controls when opening and closing the vials. To prevent formulation of potentially explosive compounds due to reactions of sodium azide and copper or lead pipes, flush waste lines with large quantities of water.

STORAGE INSTRUCTIONS

Store ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) at -20°C or colder until use. Once opened, ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) should be stored at -20°C or colder and discarded after three freeze-thaw cycles. 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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is manufactured from human serum or plasma negative for HIV-1 RNA, HCV RNA and HBV DNA, and nonreactive for HBsAg and antibodies to HIV 1 and 2, HCV and HTLV.

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. Mix the contents of the vials by gentle inversion. Return the control to -20°C or colder storage immediately after use. ACCURUN controls should be included in a test run using 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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) 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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV). When results for ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) are outside the established acceptance 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, 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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) have been established only for HIV-1 RNA, HCV RNA and HBV DNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) DOES NOT HAVE AN ASSIGNED VALUE.

This control is formulated to produce negative reactivity with the test kits listed in Table 1. 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 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is manufactured from human serum or plasma that is negative for HIV-1 RNA, HCV RNA and HBV DNA and nonreactive for HBsAg and antibodies to HIV 1 and 2, HCV and HTLV. 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 procedures 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.

Table 1. ACCURUN 803 Nucleic Acid Negative Quality Control (HIV, HCV, HBV) is formulated to produce negative reactivity (below the limits of detection) with the following test kits:

| Marker | Manufacturer | Product Name |
|-----------------------------------|-------------------------------|---|
| HIV-1 RNA | Roche Molecular Systems, Inc. | COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test v2.0 |
| HCV RNA | Roche Molecular Systems, Inc. | COBAS® AmpliPrep/ COBAS® TaqMan® HCV Test |
| HBV DNA | Roche Molecular Systems, Inc. | COBAS® AmpliPrep/ COBAS® TaqMan® HBV Test v2.0 |
| HIV-1 RNA/ HCV RNA/ HBV DNA | Gen-Probe | Procleix® Ultrio Assay |

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