# ACCURUN® 803

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

## 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.

CE 0086

EC REP

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## Explanation of symbols used in SeraCare product labeling

Harmful/Irritant

This product contains 0.09% sodium azide.

| | |
|---|---|
| R22 | Harmful if swallowed. |
| S32 | Contact with acids liberates very toxic gas. |
| S35 | This material and its container must be disposed of in a safe way. |
| S36 | Wear suitable protective clothing. |
| S46 | If swallowed, seek medical advice immediately and show this container or label. |

Upper limit of temperature

Temperature limitation

"Caution, consult accompanying documents"

Biological risks

Use By

EC REP

Authorized Representative in the European Community

CONTROL –

Negative control

REF

Catalogue number

IVD

*In Vitro* Diagnostic Medical Device

CONTROL +

Positive control

LOT

Batch code

GB

# ACCURUN® 803

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

***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® 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 sensitivity[1].

### 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
Cat. No. A803-0027 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 samples[2]. 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 days[3].

### 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

1. 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.
2. CDC *recommendations for prevention of HIV transmission in health care settings.* MMWR 36 (supp. 2), 1987.
3. *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 |
| HIV-1 RNA | Roche Molecular Systems, Inc. | COBAS AmpliScreen™ HIV-1 Test v1.5 |
| HCV RNA | Roche Molecular Systems, Inc. | COBAS® AmpliPrep/COBAS® TaqMan® HCV Test |
| HCV RNA | Roche Molecular Systems, Inc. | COBAS AmpliScreen™ HCV Test v2.0 |
| 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 001.508.244.6400.**

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