# ACCURUN® 306
## SERIES 500

HCV RNA
Positive 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, the SeraCare logo, and contact information.

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, or call us at 508.244.6400.

A printed package insert will be sent to you upon request.

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US

# ACCURUN® 306 SERIES 500

## HCV RNA Positive 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® 306 HCV RNA Positive Control Series 500 is formulated for use with laboratory tests that detect and quantitate HCV RNA. Additional controls at different concentrations of HCV RNA are available separately from SeraCare Life Sciences. *For Research Use Only. Not for use in diagnostic procedures.*

### 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 306 HCV RNA Positive Control is designed for use with laboratory testing for the purpose of monitoring test performance. ACCURUN 306 HCV RNA Positive Control is manufactured from human plasma reactive for HCV RNA genotype 1 and nonreactive for HBsAg and antibodies to HIV 1 and HIV 2 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.

### REAGENTS
Cat. No. A306-6515 10 vials, 0.5 mL per vial

ACCURUN 306 HCV RNA Positive Control contains stabilizers and 0.09% sodium azide as preservative.

### WARNINGS AND PRECAUTIONS
***For Research Use Only. Not for use in diagnostic procedures.***
CAUTION: Handle ACCURUN controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 306 HCV RNA Positive Control is manufactured from human plasma nonreactive for HBsAg and antibodies for HIV 1 and 2, and HTLV with current FDA licensed tests.

#### Safety Precautions
Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human blood[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 formation 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
For maximum stability, ACCURUN 306 HCV RNA Positive Control should be stored at -70°C. If preferred, vials may be stored at -20°C for up to six months. Once a vial has been opened and used, do not reuse.

### 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 306 HCV RNA Positive Control is manufactured from human plasma reactive for HCV RNA genotype 1 and nonreactive for HBsAg and antibodies to HIV 1 and 2 and HTLV.

#### Materials Required but not Provided
Refer to instructions supplied by manufacturers of the test kits to be used.

#### Instructions for Use
Thaw at room temperature and mix by gentle pipetting before use. Once thawed, use immediately. 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 306 HCV RNA Positive 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 306 HCV RNA Positive Control. When results for ACCURUN 306 HCV RNA Positive Control 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 306 HCV RNA Positive Control have been established only for HCV RNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

### EXPECTED RESULTS
**ACCURUN 306 HCV RNA Positive 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 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].

Table 1 lists typical data for ACCURUN 306 HCV RNA Positive Control. These data are expressed as the mean of data points in units as specified by the manufacturer.

### SPECIFIC PERFORMANCE CHARACTERISTICS
ACCURUN controls are designed for use with laboratory testing for purposes of monitoring assay performance. ACCURUN 306 HCV RNA Positive Control is manufactured from human plasma reactive for HCV RNA genotype 1 and nonreactive for HBsAg and antibodies to HIV 1 and 2 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 procedure 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:** Typical Data for ACCURUN 306 HCV RNA Positive Control Series 500.

| Analyte | Manufacturer | Test | Product Code | Mean Value |
|---|---|---|---|---|
| HCV RNA | Roche Diagnostics Raritan, NJ | COBAS® HCV Ampliprep/ COBAS® TaqMan® HCV Test | 03568555 | 9.7 x $10^5$ IU/mL |

**For assistance, contact SeraCare Technical Support at 508.244.6400.**

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