



ACCURUN[®] 325 SERIES 200

Hepatitis B Virus DNA
Positive Quality 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 0.09% 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



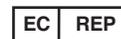
"Caution, consult accompanying documents"



Biological risks



Use By



Authorized Representative in the European Community



Negative control



Catalogue number



In Vitro Diagnostic Medical Device



Positive control



Batch code

ACCURUN[®] 325

SERIES 200

Hepatitis B Virus DNA Positive Quality Control

US

**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[®] 325 Hepatitis B Virus DNA Positive Quality Control Series 200 is formulated for use in genetic amplification based *in vitro* diagnostic test procedures that detect Hepatitis B Virus (HBV) DNA. *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 325 Hepatitis B Virus DNA Positive Quality Control Series 200 is designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 325 HBV DNA Positive Quality Control Series 200 is manufactured from human serum or plasma reactive for HBV DNA and nonreactive 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

Cat. No. A325-5228 10 vials, 1.5 mL per vial
Cat. No. A325-5232 5 vials, 4.0 mL per vial

ACCURUN 325 Hepatitis B Virus DNA Positive Quality Control Series 200 contains stabilizers 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 325 is manufactured from human serum or plasma nonreactive for 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 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. 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.

Nucleic acid amplification reactions are sensitive to amplicon contamination. Inconsistent or invalid results could occur if clinical specimens or quality control reagents become contaminated. Use aerosol barrier pipette tips in a biosafety hood or other containment facility for dispensing patient samples and controls, and open only one sample at a time. The risk of contaminating ACCURUN 325 Hepatitis B Virus DNA Positive Quality Control Series 200 will be greatly reduced by discarding the control immediately after first use.

STORAGE INSTRUCTIONS

Store ACCURUN 325 Hepatitis B Virus DNA Positive Quality Control Series 200 at -20°C or colder until use. 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 325 Hepatitis B Virus DNA Positive Quality Control Series 200 is manufactured from human serum or plasma reactive for HBV DNA and nonreactive for 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

- Prior to each use, allow the control to reach room temperature and mix by gentle inversion.
- Each vial of ACCURUN 325 should not be used more than three times and must be used within 10 days after first opening.
- Immediately after each use, refrigerate ACCURUN 325 at 2-8°C.
- When the vial is opened for the first time, record the date opened and the expiration date on the vial.
- To minimize the chance of contamination, discard the vial after first use.

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 as part of the test kit.

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 325 Hepatitis B Virus DNA Positive Quality Control Series 200 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 325. When results for ACCURUN 325 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 325 Hepatitis B Virus DNA Positive Quality Control Series 200 have been established only for Hepatitis B Virus DNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 325 Hepatitis B Virus DNA Positive Quality Control Series 200 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 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 325 Hepatitis B Virus DNA Positive Quality Control Series 200 is manufactured from human serum or plasma reactive for HBV DNA and nonreactive 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. 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.

For assistance, contact SeraCare Technical Support at 508.244.6400.