ACCURUN®

HCV RNA
Tri-Level Controls Kit

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

MEDIMARK® Europe
11, rue Émile Zola BP 2332
38033 Grenoble Cedex 2 – France
+ 33 (0) 4 76 86 43 22
info@medimark-europe.com

SeraCare LIFE SCIENCES

SeraCare Life Sciences, Inc. | 25 Birch Street, Milford, MA 01757 USA
Phone: 001.508.244.6400 | info@seracare.com

August 2015 12956GB-01

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®

HCV RNA Tri-Level Controls Kit

THESE REAGENTS MUST NOT BE SUBSTITUTED FOR ANY 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® HCV RNA Tri-Level Controls Kit is formulated for use with *in vitro* diagnostic amplified test methods that detect and quantitate Hepatitis C Virus (HCV) RNA. *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 detect immediate analytical errors and monitor long term performance of test kits, 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 HCV RNA Tri-Level Controls Kit is designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. This product is a set of external run controls for use with assays that detect and quantitate HCV. ACCURUN HCV RNA Tri-Level Controls kit is manufactured from pooled human plasma, defibrinated human plasma, and HCV RNA positive plasma and has been formulated for positive and negative reactivity with quantitative HCV RNA assays. The kit contains three controls: a high positive, a low positive, and a negative control.

REAGENTS

Item No. 2020-0141 — 15 vials/kit

5 vials of each control:
HCV RNA Tri-Level High, 1.2 ml per vial
HCV RNA Tri-Level Low, 1.2 ml per vial
HCV RNA Tri-Level Neg, 1.2 ml per vial

ACCURUN HCV RNA Tri-Level Controls Kit contains stabilizers and 0.09% sodium azide as a preservative.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use

CAUTION: Handle ACCURUN controls and all human derived products as though capable of transmitting infectious agents. ACCURUN HCV RNA Tri-Level Controls Kit is manufactured using pooled human plasma, defibrinated human plasma, and HCV RNA positive plasma.

Safety Precautions

Use Center for Disease Control and Prevention (CDC) recommended universal precautions for handling ACCURUN and human specimens[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 controls, specimens and materials used in testing as though they contain infectious agents[3].

Handling Precautions

Do not use ACCURUN controls beyond the expiration date. Avoid contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN HCV RNA Tri-Level Controls Kit at -70 °C or colder until use. Once opened, an individual vial of ACCURUN Tri-Level Control should not be reused. Store vials upright to prevent leakage.

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 HCV RNA Tri-Level Controls kit is manufactured from pooled human plasma, defibrinated human plasma, and HCV RNA. It also contains human proteins and preservatives.

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 come to room temperature and mix the contents of the vials by gentle inversion before use. Once thawed, use immediately. 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 the manufactured test kits.

QUALITY CONTROL

Since ACCURUN HCV RNA Tri-Level 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 HCV RNA Tri-Level Controls may vary with different manufacturers' tests and different test kit lots. Since the controls do not have assigned values, the laboratory must establish a range for each lot of each control. When results for ACCURUN HCV RNA Tri-Level Controls are outside of the established acceptance range for any of the three controls, it may indicate 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 ANY 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 HCV RNA Tri-Level Controls Kit have been established only for amplified nucleic acid tests that detect HCV RNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN HCV RNA Tri-Level Controls Kit DOES NOT HAVE ASSIGNED VALUES. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories. ACCURUN HCV RNA Tri-Level Controls Kit contains a high positive control, a low positive control, and a negative control. Each control is formulated to produce different results. Each laboratory should establish its own range of acceptable values for each individual control. Refer to Table 1 for typical results for each control in the ACCURUN HCV RNA Tri-Level Controls Kit.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* diagnostic assay procedures for the purposes of monitoring assay performance. ACCURUN controls do not have assigned values. 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. *Treatment Standards for hazardous waste;* 40 CFR268.40; Subpart D. D001: Ignitable characteristics of waste.

Table 1. Typical Data for ACCURUN HCV RNA Tri-Level Controls Kit.

ACCURUN HCV RNA Tri-Level Control	Analyte	Test	Typical Results
HCV RNA Tri-Level High Control	HCV RNA	Roche COBAS® AmpliPrep/ COBAS® TaqMan® HCV RNA	1,418,096 IU/ml
HCV RNA Tri-Level Low Control	HCV RNA	Roche COBAS® AmpliPrep/ COBAS® TaqMan® HCV RNA	1914 IU/ml
HCV RNA Tri-Level Neg. Control	HCV RNA	Roche COBAS® AmpliPrep/ COBAS® TaqMan® HCV RNA	BLD

For assistance, contact SeraCare Technical Support at 001.508.244.6400.

August 2015 12956GB-01

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PHONE: 001.508.244.6400 | FAX: 001.508.634.3394 | Toll Free (US only): 800.676.1881 | www.seracare.com