



ACCURUN[®] 501

C. difficile 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.



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

July 2014 12774GB-02

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



Biological risks



Negative control



Positive control



Temperature limitation



Use By



Catalogue number



Control



"Caution, consult accompanying documents"



Authorized Representative in the European Community



In Vitro Diagnostic Medical Device



Batch code

THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

ACCURUN products are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 501 C. difficile Control is formulated for use with *in vitro* diagnostic test methods that detect C. difficile DNA in human stool samples. *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 allows 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 sensitivity¹.

PRINCIPLES OF THE PROCEDURE

ACCURUN 501 C. difficile Control is designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 501 C. difficile Control is manufactured from cultured Clostridium bacteria of four different strains or species. The bacteria are inactivated and in a human synthetic stool matrix. The control is "ready to use" in assays that detect C. difficile DNA.

Vial A501-01 (red capped tube) contains cultured C. difficile NAP1/027/B1 hypervirulent strain (strain 4118).

Vial A501-02 (red capped tube) contains cultured toxigenic C. difficile strain (strain VPI 10463).

Vial A501-03 (white capped tube) contains cultured non-toxicogenic C. difficile strain (strain 1351).

Vial A501-04 (white capped tube) contains cultured Clostridium sordellii (strain 211 [NCIB 10717]).

REAGENTS

Item No. 2050-0008	A501-01	1 vial, 0.6 ml per vial
	A501-02	1 vial, 0.6 ml per vial
	A501-03	1 vial, 0.6 ml per vial
	A501-04	1 vial, 0.6 ml per vial

ACCURUN 501 C. difficile Control is formulated in synthetic stool which contains human proteins and genomic DNA, 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 501 C. difficile Control is manufactured from cultured Clostridium bacteria including C. difficile and C. sordellii.

SAFETY PRECAUTIONS

Use Center for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human specimens². 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 and materials used in testing as though they contain infectious agents.

HANDLING PRECAUTIONS

Do not use ACCURUN 501 C. difficile Control beyond the expiration date. Avoid contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN 501 C. difficile Control at -20 °C until use. Once opened, an individual vial of ACCURUN 501 C. difficile Control should not be reused.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

ACCURUN 501 C. difficile Control is a suspension of bacterial cells in synthetic human stool and therefore appears as an opaque, brown, slightly viscous liquid. Alterations in this appearance or visible microbial growth may indicate instability or deterioration of the control and such solutions should be discarded.

PROCEDURE

Materials Provided

ACCURUN 501 C. difficile Control, vial A501-01, is manufactured from cultured hypervirulent C. difficile NAP1/027/B1 and serves as a positive control for detection of toxigenic C. difficile containing the Toxin B gene, Binary Toxin gene and missense mutation in TcdC gene.

ACCURUN 501 C. difficile Control, vial A501-02, is manufactured from cultured toxigenic C. difficile and serves as a positive control for detection of toxigenic C. difficile containing the Toxin B gene.

ACCURUN 501 C. difficile Control, vial A501-03, is manufactured from cultured non-toxicogenic C. difficile and serves as a negative control for detection of toxigenic C. difficile.

ACCURUN 501 C. difficile Control, vial A501-04, is manufactured from cultured C. sordellii and serves as a negative control for detection of C. difficile.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

INSTRUCTIONS FOR USE

Allow the control vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous cell suspension. ACCURUN Controls should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. Process the ACCURUN 501 C. difficile Control according to the instructions for unknown samples provided by the diagnostic test kit or the laboratory's standard operating procedures. ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

QUALITY CONTROL

Since ACCURUN 501 C. difficile Control does not have assigned values, it is recommended that each laboratory qualify the use of each lot of ACCURUN 501 C. difficile Control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 501 C. difficile 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 501 C. difficile Control. When results for ACCURUN 501 C. difficile Control are outside of the established acceptance range, 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 THE 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 501 C. difficile Control have been established only for C. difficile DNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN 501 C. difficile Control DOES 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. 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 20 days³.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* diagnostic assay procedures for the purposes of monitoring assay performance. ACCURUN 501 C. difficile Control is manufactured from cultured Clostridium bacteria that are inactivated and formulated in a human synthetic stool matrix. 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.
- CDC Recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp. 2), 1987.
- Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline— Second Edition. NCCLS document C24-A2, 1999.

Table 1. Typical Data for ACCURUN 501 C. difficile Control.

A501 Vial	Cap Color	Content	Expected Results for Toxigenic C. difficile Detection
A501-01	Red	C. difficile Hypervirulent NAP1/027/B1	Positive
A501-02	Red	C. difficile Toxigenic	Positive
A501-03	White	C. difficile Non-toxicogenic	Negative
A501-04	White	C. sordellii	Negative

For assistance, contact SeraCare Technical Support at 001.508.244.6400.