ACCURUN® 501

C. difficile Control

CE

EC REP

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Explanation of symbols used in SeraCare product labeling

Upper limit of temperature

Temperature limitation

EC REP

Authorized Representative in the European Community

Biological risks

Use By

IVD

In Vitro Diagnostic Medical Device

CONTROL -

Negative control

REF

Catalogue number

Consult instructions for use

CONTROL +

Positive control

LOT

Batch code

Manufacturer

CONTROL

Control

Highly Flammable

Toxic by inhalation, in contact with skin and if swallowed

Health Hazard

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

ACCURUN® 501 *C. difficile* Control

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 sensitivity[1].

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-toxigenic *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 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 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-toxigenic *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 days[3].

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

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. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
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 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-toxigenic	Negative
A501-04	White	*C. sordellii*	Negative

For assistance, contact SeraCare Technical Support at +1 508.244.6400.

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