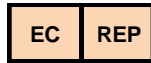


ACCURUN® 342 SERIES 100

Chlamydia trachomatis *Neisseria gonorrhoeae*
Positive Control



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Explanation of symbols used in SeraCare product labeling



Upper limit of temperature



Temperature limitation



Authorized Representative in
the European Community



Biological risks



Use By



In Vitro Diagnostic Medical Device



Negative control



Catalogue number



Consult instructions for use



Positive control



Batch code



Manufacturer



Control



Highly Flammable



Toxic by inhalation, in contact
with skin and if swallowed



Health Hazard

ACCURUN® 342 SERIES 100 *Chlamydia trachomatis* *Neisseria gonorrhoeae*

Positive 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® 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 is formulated for use with *in vitro* diagnostic amplified test methods that detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* nucleic acids. 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 sensitivity¹.

PRINCIPLES OF THE PROCEDURE

ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 has been designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 is manufactured by diluting elementary bodies derived from cultured *Chlamydia trachomatis* and cultured *Neisseria gonorrhoeae* in a buffer simulating specimen transport media that contains the human cellular components required to obtain valid positive results on assay platforms in an aqueous solution. The control contains whole organisms simulating the naturally occurring sample through the specimen lysis and all subsequent steps in the procedure.

REAGENTS

Item No. 2025-0067 10 vials, 1.0 mL per vial

ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 contains stabilizers and 0.05% sodium azide and 0.05% gentamicin as preservatives.

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 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 is manufactured using human cellular components in a buffered aqueous solution containing human proteins intended to simulate specimen transport media.

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 controls, specimens and materials used in testing as though they contain infectious agents³.

Handling Precautions

Do not use ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 beyond the expiration date. Avoid contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 at 2-8°C until use. Once opened, an individual vial of ACCURUN 342 Series 100 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 342 Series 100 is manufactured using components from cultured human cells. It also contains buffers, human proteins, and preservatives.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used. Pipettes with aerosol barrier tips or positive displacement tips should be used with this product.

Instructions for Use

Allow the controls to come to room temperature before use. Mix the contents of the vials by vortexing or inversion. 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 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 does not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN with each specific test system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Since the ACCURUN 342 Series 100 control does not have an assigned value, the laboratory must establish a range for each lot of product. When results for ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 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 342 Positive Control Series 100 have been established only for amplified nucleic acid tests that detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100 DOES NOT HAVE ASSIGNED VALUES. This control is formulated to produce valid positive results listed in Table 1. Each laboratory should establish its own range of acceptable values.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* diagnostic assay procedures for the purposes of monitoring assay performance. 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.
- 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.
- Treatment Standards for hazardous waste; 40 CFR268.40; Subpart D. D001: Ignitable characteristics of waste.

Table 1. Typical Data for ACCURUN 342 *Chlamydia trachomatis* *Neisseria gonorrhoeae* Positive Control Series 100.

Typical Data	
<i>Chlamydia trachomatis</i>	Positive
<i>Neisseria gonorrhoeae</i>	Positive

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