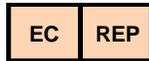


ACCURUN® 841

Chlamydia trachomatis
Neisseria gonorrhoea
Negative 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® 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative 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® 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control is formulated for use with *in vitro* diagnostic amplified test methods that detect *Chlamydia trachomatis* *Neisseria gonorrhoea* nucleic acid. 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 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control has been designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control is manufactured in a buffer simulating specimen transport media that contains the human cellular components required to obtain valid negative results on assay platforms. A841 contains human proteins and genomic DNA.

REAGENTS

Item No. 2025-0061 10 vials, 1 ml per vial

ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control 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 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control 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 specimens and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control beyond the expiration date. Avoid contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control at 2-8 °C until use. Once opened, an individual vial of ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control should not be reused. Store vials upright to minimize 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 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control 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.

Cepheid Xpert® CT/NG Assay³:

Obtain an Xpert CT/NG Assay Cartridge, a transfer pipette provided with the assay kit and the vial of A841 Control. Open the cartridge lid and ensure that the control is well mixed. Unwrap the transfer pipette, compress the bulb of the pipette and insert the pipette into the vial of A841 control. Release the bulb to fill the transfer pipette above the mark on the pipette shaft, making sure that there are no air bubbles present. Empty the pipette's content into the Sample (S) chamber of the assay cartridge. Close the cartridge lid and process the cartridge using the GeneXpert system.

Quality Control

Since ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control does not have assigned values, it is recommended that each laboratory qualify the use of each lot of ACCURUN with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Since the ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control does not have an assigned value, the laboratory must establish a range for each lot of product. When results for ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative 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 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control have been established only for amplified nucleic acid tests to detect *Chlamydia trachomatis* *Neisseria gonorrhoea* DNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN 841 CHLAMYDIA TRACHOMATIS NEISSERIA GONORRHEA NEGATIVE CONTROL DOES NOT HAVE ASSIGNED VALUES. This control is formulated to produce valid negative results listed in Table 1. 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 30 days⁴.

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, Shabelsky LA, Achord D, Page E, and Le AV. Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality 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.
- Cepheid Xpert® CT/NG Assay kit (Cat. No. GXCT/NG-10) Package insert (301-0234, Rev. B January 2013). Cepheid, Sunnyvale, CA 94089-1189 USA.
- Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline—Second Edition. NCCLS document C24-A2, 1999.

Table 1. Typical Data for ACCURUN 841 *Chlamydia trachomatis* *Neisseria gonorrhoea* Negative Control.

Manufacturer	Assay	Typical Data
Cepheid	Xpert® CT/NG	CT Not Detected NG Not Detected

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