ACCURUN® 841

Chlamydia trachomatis
Neisseria gonorrhea
Negative 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.

CE 0086

EC REP

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Explanation of symbols used in SeraCare product labeling

Harmful/Irritant

This product contains 0.05% 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

ACCURUN® 841

GB

Chlamydia trachomatis
Neisseria gonorrhea
Negative Control

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® 841 *Chlamydia trachomatis Neisseria gonorrhea* Negative Control is formulated for use with *in vitro* diagnostic amplified test methods that detect *Chlamydia trachomatis Neisseria gonorrhea* 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 sensitivity[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN 841 *Chlamydia trachomatis Neisseria gonorrhea* 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 gonorrhea* 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 gonorrhea* 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 gonorrhea* 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 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 841 *Chlamydia trachomatis Neisseria gonorrhea* 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 gonorrhea* Negative Control at 2-8 ºC until use. Once opened, an individual vial of ACCURUN 841 *Chlamydia trachomatis Neisseria gonorrhea* 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 gonorrhea* 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 Assay[3]:

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 gonorrhea* 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 gonorrhea* 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 gonorrhea* 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 gonorrhea* Negative Control have been established only for amplified nucleic acid tests to detect *Chlamydia trachomatis Neisseria gonorrhea* 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 days[4].

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

1. Green IV GA, Carey RN, Westgard JO, Carten T, Shabelsky LA, Achord D, Page E, and Le AV *Quality control for qualitative assays: quantitiative QC procedure designed to assure analytical quality 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. 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.
4. *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 gonorrhea* Negative Control.

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

For assistance, contact SeraCare Technical Support at 001.508.244.6400.

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