ACCURUN® 841

Chlamydia trachomatis
Neisseria gonorrhea
Negative Control

CE 2797

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

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

ACCURUN® 841 *Chlamydia trachomatis Neisseria gonorrhea* 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 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 Centers 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 °C 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.

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[3].

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. 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 841 *Chlamydia trachomatis Neisseria gonorrhea* Negative Control.

Typical Data
CT Not Detected
NG Not Detected

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