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.

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

Authorized Representative in the European Community

Negative control

Catalogue number

In Vitro Diagnostic Medical Device

Positive control

Batch code
**ACCURUN Controls**

**Chlamydia trachomatis**

**Neisseria gonorrhoeae**

**Positive Control**

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**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 sensitivity.

**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 specimens.

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 agents.

**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 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.

**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**


3. 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.**

<table>
<thead>
<tr>
<th>Typical Data</th>
<th>Chlamydia trachomatis</th>
<th>Neisseria gonorrhoeae</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>

For assistance, contact SeraCare Technical Support at 001.508.244.6400.