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.

Explanations 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
- **Biological risks**: “Caution, consult accompanying documents”
- **Use By**: Authorized Representative in the European Community
- **Negative control**: Catalogue number
- **Positive control**: In Vitro Diagnostic Medical Device
- **Batch code**:
ACCURUN® 342
SERIES 100
Chlamydia trachomatis
Neisseria gonorrhoeae
Positive Control

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
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>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
</tbody>
</table>

For assistance, contact SeraCare Technical Support at 1.508.244.6400.