

## About this package insert

Thank you for your interest in this ACCURUN<sup>®</sup> product. This package insert consists of two pages.

The first page contains the product name, the LGC logo, and contact information.

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 [CDx-Info@LGCGroup.com](mailto:CDx-Info@LGCGroup.com), or call us at +1.508.244.6400.

A printed package insert will be sent to you upon request.



# ACCURUN<sup>®</sup> MS2 Internal Control

## NAME AND INTENDED USE

ACCURUN<sup>®</sup> MS2 Internal Control is formulated for use as a full internal control for any nucleic acid amplification-based assays. ACCURUN MS2 Internal Control contains MS2 bacteriophage that is diluted to an appropriate concentration for spiking as an internal control into nucleic acid amplification-based reactions. ACCURUN MS2 Internal Control can be used to monitor assay performance and to ensure extraction and amplification steps (and associated reagents) are working properly. *For Research Use only. Not for use in diagnostic procedures.*

## SUMMARY

Diagnostic developers and analysts rely on positive disease state materials that can effectively challenge all elements of an assay from sample preparation through amplification and detection. A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of internal controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity.

## PRINCIPLES OF THE PROCEDURE

ACCURUN MS2 Internal Control is designed for use as a full process internal control for nucleic acid amplification-based assays. The product is ready-to-use for extraction and detection via amplified nucleic acid tests.

ACCURUN MS2 Internal Control contains MS2 bacteriophage that is diluted in a stabilizing buffer to the target concentration (10,000,000 copies/mL) for spiking as an internal control into nucleic acid amplification reactions.

## REAGENTS

Item No.: 2020-0160

1 vial, 1 mL per vial

ACCURUN MS2 Internal Control is formulated in MS2 bacteriophage diluted to the target concentration in SM buffer.

## WARNINGS AND PRECAUTIONS

*For Research Use only. Not for use in diagnostic procedures.*

CAUTION: Handle ACCURUN products as though capable of transmitting infectious agents.

### Safety Precautions

Use Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human specimens<sup>1</sup>. 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 MS2 Internal Control beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

## STORAGE INSTRUCTIONS

Store ACCURUN MS2 Internal Control at 2-8 °C until use. Once opened, an individual vial of ACCURUN MS2 Internal Control should not be reused.

## INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

ACCURUN MS2 Internal Control is a mixture of MS2 bacteriophage in a stabilizing buffer. Alterations in this appearance or visible microbial growth may indicate instability or deterioration of the product and vials should be discarded.

## PROCEDURE

### Materials Provided

ACCURUN MS2 Internal Control is manufactured using MS2 bacteriophage and a stabilizing buffer.

## Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

## Instructions for Use

Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous suspension. ACCURUN Internal Controls should be added to a test run using the same instructions provided by the manufacturer kit or the laboratory's standard operating procedures for unknown specimens. ACCURUN MS2 Internal Controls must go through an extraction process prior to amplification and detection by PCR. ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

## Quality Control

Since ACCURUN MS2 Internal Control does not have assigned values, it is recommended that each laboratory qualify the use of each lot of ACCURUN MS2 Internal Control with each specific assay system prior to its routine use in the laboratory.

## INTERPRETATION OF RESULTS

Results for ACCURUN MS2 Internal Control may vary with different types of tests and different test kit lots. Unexpected results 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. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

## EXPECTED RESULTS

**ACCURUN MS2 Internal Control DOES NOT HAVE ASSIGNED VALUES.** 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.

## SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with test procedures for the purposes of assessing amplification performance. ACCURUN MS2 Internal Controls are manufactured from cultured MS2 bacteriophage. ACCURUN controls do not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

## REFERENCES

1. 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.

Table 1. Typical Data for ACCURUN MS2 Internal Control

Content	Expected Results
ACCURUN MS2 Internal Control	Positive

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.