

# ACCURUN® 873 HPV DNA Negative Control

## NAME AND INTENDED USE

ACCURUN® Controls are intended for use as qualitative controls to monitor laboratory testing precision and detect errors in laboratory testing procedures. ACCURUN 873 HPV DNA Negative Control is formulated for use with *in vitro* diagnostic test methods that detect HPV DNA in human cervical samples collected in PreservCyt® transport medium. ACCURUN controls do not have quantitative assigned values. For professional laboratory use only.

## 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 monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, 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<sup>1</sup>.

## PRINCIPLES OF THE PROCEDURE

ACCURUN controls are designed for use with *in vitro* assay procedures for the purpose of monitoring assay performance. ACCURUN 873 HPV DNA Negative Control is manufactured from cultured human cells preserved in PreservCyt®2 solution.

ACCURUN controls do not have assigned values. Examples of assay(s) with which this control may be compatible are listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

## REAGENTS

Item No. 2035-0005 20 vials, 4.0 ml per vial

ACCURUN 873 HPV DNA Negative Control contains buffered methanol<sup>2</sup>.

## WARNINGS AND PRECAUTIONS

### For *In Vitro* Diagnostic Use.

CAUTION: Handle ACCURUN controls and all human blood products as though capable of transmitting infectious agents. ACCURUN 873 HPV DNA Negative Control is manufactured from human cells that are grown in tissue culture and preserved in PreservCyt®2 solution.

### Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN controls and human blood<sup>3</sup>. Do not pipette by mouth; do not 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, controls and materials used in testing as though they contain infectious agents. Additional safety information can be found in the product Safety Data Sheet (SDS) found on the company website.

ACCURUN 873 HPV DNA Negative Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste<sup>4</sup>. Keep ACCURUN 873 HPV DNA Negative Control closed when not in use; avoid direct inhalation of the solution and use with adequate ventilation.

### Handling Precautions

Do not use ACCURUN controls beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

FLAMMABLE keep away from all sources of ignition.

## STORAGE INSTRUCTIONS

Store ACCURUN 873 HPV DNA Negative Control at 2-8°C until use. Once opened, ACCURUN 873 should not be reused. To prevent leakage, store vials upright.

## INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

ACCURUN 873 HPV DNA Negative Control is a suspension of fixed cells in solution and may therefore exhibit slight cloudiness. Excessive turbidity may indicate instability or deterioration of ACCURUN 873, and such solutions should be discarded.

## PROCEDURE

### Materials Provided

ACCURUN 873 HPV DNA Negative Control is manufactured from human cells grown in tissue culture and preserved in buffered methanol solution. See REAGENTS for a list of package sizes.

### Materials Required but not Provided

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

### Instructions for Use

- Remove the controls from refrigerator storage and allow to equilibrate to room temperature.
- Mix by vortexing for 15 seconds to assure a homogeneous cell suspension.
- For the Qiagen hc2 High-Risk HPV DNA Test, use the entire sample and process per the test kit instructions for an unknown specimen.
- For the Roche cobas® HPV Test, pipette 1 ml of the cell suspension into the Roche recommended tube and process per the test kit instructions for an unknown specimen.
- ACCURUN 873 HPV DNA Negative Control should be included in a test run using exactly the same procedure that is used to run the unknown specimens collected in PreservCyt®2 solution.
- ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with test kits.

## Quality Control

Since ACCURUN controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN with each specific assay system prior to its routine use in the laboratory.

## INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN Controls may vary with different manufacturers' tests and different test kit lots. Each laboratory must establish its own range of acceptable values for ACCURUN controls with the particular test kits being used. When results for ACCURUN controls are outside the established acceptable range of values, it may be an indication of 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 POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and INTERPRETATION OF RESULTS provided by manufacturers of test kits must be followed. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN controls are qualitative, not automated, and are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

## EXPECTED RESULTS

**ACCURUN CONTROLS DO NOT HAVE ASSIGNED VALUES.** This control is formulated to produce negative reactivity for the analytes listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values for each analyte. 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<sup>5</sup>.

## SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls are designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 873 HPV DNA Negative Control is manufactured from human cells that are grown in tissue culture and preserved in PreservCyt®2 solution. ACCURUN controls do not have assigned values. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent 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. Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

## ACKNOWLEDGEMENT

The cultured cells used in this product are under licensing agreement with NIH.

## REFERENCES

- Green IV GA, Carey RN, Westgard JO, Carten T, Shablesky LA, Achord D, Page E, and Le AV. Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin. Chem. 43:9 1618-1621, 1997.
- Hologic PreservCyt® Solution Package Insert part number 85177-001, Rev. I. Hologic, Inc. 250 Campus Drive, Marlborough, MA 01752.
- 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.
- Treatment standards for hazardous waste; 40 CFR 268.40; Subpart D. D001: Ignitable characteristics of waste.
- Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline— Fourth Edition. CLSI document C24, 2016.

**Table 1.** This product is tested using the following assays. Results are for information only, not assigned values.

Manufacturer	Assay	Typical Data
Qiagen: Valencia, CA	Qiagen HC2 High-Risk HPV DNA Test	Negative
Roche: Indianapolis, IN	cobas® 4800 HPV DNA Test	HPV16: Negative HPV18: Negative Other HR HPV: Negative

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

Any serious incident that has occurred in relation to the device shall be reported to LGC Clinical Diagnostics Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date	Description of Change
February 2026	Update for IVDR specific changes and remove Cervista assay.

# ACCURUN<sup>®</sup> 873

HPV DNA Negative Control



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## Legend of all symbols used in LGC product labeling



Upper limit of temperature



Temperature limitation



Authorized Representative in  
the European Community



Biological risks



Use By



*In Vitro* Diagnostic Medical Device



Negative control



Catalogue number



Consult instructions for use



Positive control



Batch code



Manufacturer



Control



Highly Flammable



Toxic by inhalation, in contact  
with skin and if swallowed



Health Hazard



Single use



Importer