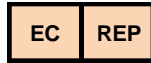


ACCURUN® 873

HPV DNA Negative Control



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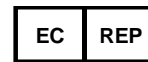
Explanation of symbols used in LGC Clinical Diagnostics product labeling



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

ACCURUN® 873 HPV DNA Negative Control

NAME AND INTENDED USE

ACCURUN whole cell controls are designed to evaluate laboratory testing precision and can be used to 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. 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 that closely mimic patient samples allows laboratories to detect immediate analytical errors and monitor long-term performance and can assist in identifying increases in random or systematic errors. A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent whole cell controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity¹.

PRINCIPLES OF THE PROCEDURE

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

REAGENTS

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

ACCURUN 873 HPV DNA Negative Control contains buffered methanol².

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 Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human specimens³. 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, controls, and materials used in testing as though they contain infectious agents.

ACCURUN 873 HPV DNA Negative Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste⁴. 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 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. Store vials upright to prevent leakage.

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.

Materials Required but not Provided

Refer to instructions supplied by manufacturer of the test kit 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 Cervista HPV HR Test, pipette 2 ml of the cell suspension and extract DNA using the Genfind extraction kit; detect HPV signal using the Cervista HPV HR assay.
- 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 the manufactured testkits.

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 873 HPV DNA Negative Control may vary with different manufacturers' tests and different test kit lots. Since the control does not have an assigned value, the laboratory must establish a range for each lot of ACCURUN 873 HPV DNA Negative Control. When results for ACCURUN 873 HPV DNA Negative Control are outside the established acceptance range of values, it may be an indication of unsatisfactory test performance. Possible sources of discrepancy 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 NEGATIVE 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 873 HPV DNA Negative Control have been established only for HPV DNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 873 HPV DNA Negative Control DOES NOT HAVE AN ASSIGNED VALUE. 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. 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 days⁵.

Table 1 lists typical data for ACCURUN 873 HPV DNA Negative Control. These data are expressed as specified by the assay manufacturer.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* assay procedures for the purposes of monitoring assay performance. ACCURUN 873 HPV DNA Negative Control is manufactured from human cells obtained from tissue culture and diluted in PreservCyt®2 solution. ACCURUN controls do 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.

ACKNOWLEDGEMENT

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

REFERENCES

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- 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—Second Edition. NCCLS document C24-A2, 1999.

Table 1. Typical Data for ACCURUN 873 HPV DNA Negative Control.

Manufacturer	Assay	Typical Data
Qiagen: Valencia, CA	Qiagen hc2 High-Risk HPV DNA Test	Negative
Hologic: Bedford, MA	Cervista™ HPV HR	Negative
Roche: Indianapolis, IN	cobas® HPV Test	HPV16: Negative HPV18: Negative Other HR HPV: Negative

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