ACCURUN® 872

HPV DNA Negative Control

CE

EC REP

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Explanation of symbols used in LGC Clinical Diagnostics product labeling

Upper limit of temperature

Temperature limitation

EC REP

Authorized Representative in the European Community

Biological risks

Use By

IVD

In Vitro Diagnostic Medical Device

CONTROL -

Negative control

REF

Catalogue number

Consult instructions for use

CONTROL +

Positive control

LOT

Batch code

Manufacturer

CONTROL

Control

Highly Flammable

Toxic by inhalation, in contact with skin and if swallowed

Health Hazard

US | THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

ACCURUN® 872 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® 872 HPV DNA Negative Control is formulated for use with *in vitro* diagnostic test methods that detect HPV DNA in human cervical samples collected in an ethanol based 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 sensitivity [1].

PRINCIPLES OF THE PROCEDURE
ACCURUN 872 HPV DNA Negative Control is designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 872 HPV DNA Negative Control is manufactured from cultured human cells preserved in an ethanol solution. A separate diluent vial containing an ethanol based transport medium is supplied with each cell suspension vial. The diluent is added to the cell suspension vial, the resulting solution is mixed, and the sample is processed according to the procedure for testing unknown samples.

REAGENTS
Item No. 2035-0009	10 vials, 1.0 ml cell suspension per vial 10 vials, 1.0 ml diluent per vial

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 872 HPV DNA Negative Control is manufactured from human cells that are grown in tissue culture and preserved in ethanol solution.

Safety Precautions
Use Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human specimens [2]. 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 872 HPV DNA Negative Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste [3]. Keep ACCURUN 872 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 872 HPV DNA Negative Control at 2-8°C until use. Once opened, ACCURUN 872 should not be reused. Store vials upright to prevent leakage.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
ACCURUN 872 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 872 and such solutions should be discarded.

PROCEDURE
Materials Provided
ACCURUN 872 HPV DNA Negative Control is manufactured from human cells grown in tissue culture and preserved in ethanol solution.

Materials Required but not Provided
Refer to instructions supplied by manufacturer of the test kit to be used.

Instructions for Use
- Remove one vial labeled "Negative Control" (cells in conical centrifuge tube) and one vial labeled "Diluent" (in flat bottomed tube) from refrigerator storage and allow to equilibrate to room temperature.
- Add the contents of the Diluent vial to the Negative Control vial. Make sure the Diluent is added to the Negative Control tube; do not attempt to reverse the procedure. Do not transfer the control into a new centrifuge tube.
- Mix by vortexing for 15 seconds to assure a homogeneous cell suspension.
- The cell suspension should be used immediately.
- ACCURUN 872 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 an ethanol based transport medium.

ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with the manufactured 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 872 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 872 HPV DNA Negative Control. When results for ACCURUN 872 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 872 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 872 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 days [4].

SPECIFIC PERFORMANCE CHARACTERISTICS
ACCURUN controls have been designed for use with *in vitro* assay procedures for the purposes of monitoring assay performance. ACCURUN 872 HPV DNA Negative Control is manufactured from human cells obtained from tissue culture and diluted in ethanol 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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2. 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.
3. Treatment standards for hazardous waste; 40 CFR 268.40; Subpart D. D001: Ignitable characteristics of waste.
4. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Second Edition. NCCLS document C24-A2, 1999.

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