ACCURUN® 372 SERIES 400

HPV DNA Positive Control

CE

EC REP

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Explanation of symbols used in SeraCare 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® 372 SERIES 400 HPV DNA Positive 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® 372 HPV DNA Positive Control Series 400 is formulated for use with laboratory tests that detect Human Papillomavirus (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 372 HPV DNA Positive Control Series 400 is designed for use with laboratory testing for HPV DNA, to monitor test performance. ACCURUN 372 HPV DNA Positive Control Series 400 is manufactured from cultured human epithelial cells (SiHa) that contain an integrated genome of HPV type 16[2]. SiHa cells are mixed with noninfected cultured human cells and suspended in a buffered 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. 2025-0037	10 vials, 0.8 mL cell suspension per vial 10 vials, 2.0 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 372 HPV DNA Positive Control Series 400 is manufactured from HPV infected human epithelial cells and other non-infected cells that are grown in tissue culture and preserved in a buffered solution.

Safety Precautions

Use Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human specimens[3]. 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 372 HPV DNA Positive Control Series 400 must be disposed of by following RCRA ID#D001 guidelines for ignitable waste[4]. Keep ACCURUN 372 HPV DNA Positive Control Series 400 closed when not in use; avoid direct inhalation of the solution and use with ventilation.

Handling Precautions

Do not use ACCURUN controls beyond the expiration date. Avoid contamination of controls when opening and closing the vials. ACCURUN 372 diluent contains a FLAMMABLE liquid; keep away from all sources of ignition.

STORAGE INSTRUCTIONS

Store ACCURUN 372 HPV DNA Positive Control Series 400 at 2-8°C until use. Once opened, ACCURUN 372 should not be reused. Store vials upright to prevent leakage.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

ACCURUN 372 HPV DNA Positive Control Series 400 contains a suspension of fixed cells in buffered solution and may therefore exhibit slight cloudiness. Excessive turbidity may indicate instability or deterioration of ACCURUN 372 and such solutions should be discarded.

PROCEDURE

Materials Provided

ACCURUN 372 HPV DNA Positive Control Series 400 is manufactured from HPV infected human epithelial cells and other non-infected cells that are grown in tissue culture and suspended in buffered 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 “Positive Control” (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 Positive Control vial. Make sure the Diluent is added to the Positive Control; do not attempt to reverse the procedure.
- Mix by vortexing for 15 seconds to assure a homogeneous cell suspension.
- The cell suspension should be used immediately.
- ACCURUN 372 HPV DNA Positive Control Series 400 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 kit.

Quality Control

ACCURUN 372 HPV DNA Positive Control Series 400 does not have an assigned value. It is recommended that each laboratory establish an acceptance range for each lot of ACCURUN 372 with each assay procedure prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 372 HPV DNA Positive Control Series 400 may vary with different manufacturer’s tests and different test kit lots. Since the control does not have an assigned value, the laboratory must establish an acceptance range for each lot of ACCURUN 372 HPV DNA Positive Control Series 400. When results for ACCURUN 372 are outside of the established acceptance range, 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 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 372 HPV DNA Positive Control Series 400 have been established only for HPV DNA. Adverse shipping and storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN 372 HPV DNA Positive Control Series 400 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[5].

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN Controls are designed for use with laboratory testing for the purposes of monitoring assay performance. ACCURUN 372 HPV DNA Positive Control Series 400 is manufactured from human epithelial cells obtained from tissue culture, mixed with non-infected cells suspended in buffered solution, and is supplied with a separate vial of an ethanol based transport medium. 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 SiHa cells used in this product were developed by Dr. Yohei Ito[2] and were provided in accordance with a Biological Agreement with the U.S. Public Health Services.

REFERENCES

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