ACCURUN® 381

HPV Type 16 and 18 mRNA Positive 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® 381 HPV Type 16 and 18 mRNA Positive Control

NAME AND INTENDED USE

ACCURUN products are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 381 HPV Type 16 and 18 mRNA Positive Control is formulated for use with *in vitro* diagnostic test methods that detect HPV mRNA in human cervical samples. *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 allows laboratories to detect immediate analytical errors and monitor long term performance of test kits, 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[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control is designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control is manufactured from cultured human cells infected with HPV type 16 or type 18 that has integrated into the cellular genome. The cells bear the mRNA transcribed from the viral genes and are preserved in a buffered methanol solution. The control is "ready to use" in assays that detect high risk HPV mRNA of E6 and E7 viral genes.

Vial A381-01 contains cultured human cells containing integrated HPV type 16 mixed with non-infected cells from tissue culture.

Vial A381-02 contains cultured human cells containing integrated HPV type 18 mixed with non-infected cells from tissue culture.

REAGENTS

Item No. 2025-0060	A381-01	10 vials, 1 mL per vial
	A381-02	10 vials, 1 mL per vial

ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control contains buffered methanol.

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 381 HPV Type 16 and 18 mRNA Positive Control is manufactured from human cells infected with HPV and non-infected human cells that are grown in tissue culture and are preserved in a buffered methanol 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 and materials used in testing as though they contain infectious agents. ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control must be disposed of by following RCRA ID#D001 guidelines for ignitable waste[3]. Keep ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control closed when not in use; avoid inhalation of the solution and use with adequate ventilation.

Handling Precautions

Do not use ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control 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 381 HPV Type 16 and 18 mRNA Positive Control at 2-8°C until use. Once opened, an individual vial of ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control should not be reused. Store vials upright to prevent leakage.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control is a suspension of fixed cells in buffered methanol solution and may therefore exhibit slight cloudiness. Excessive turbidity may indicate instability or deterioration of the control and such solutions should be discarded.

PROCEDURE

Materials Provided

ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control, vial A381-01, is manufactured from cultured human cells bearing HPV type 16 integrated into the cellular genome and also contains other non-infected human cells that are grown in tissue culture and are preserved in a buffered methanol solution.

ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control, vial A381-02, is manufactured from cultured human cells bearing HPV type 18 integrated into the cellular genome and also contains other non-infected human cells that are grown in tissue culture and are preserved in a buffered methanol solution.

Materials Required but not Provided

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

Instructions for Use

Allow the control vial to come to room temperature before use. Vortex for 3 to 10 seconds to ensure a homogeneous cell suspension. ACCURUN controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens collected in liquid Pap smear procedures. ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

Quality Control

Since ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control does not have assigned values, it is recommended that each laboratory qualify the use of each lot of ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 381 HPV Type 16 and 18 mRNA Positive 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 381 HPV Type 16 and 18 mRNA Positive Control. When results for ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control are outside of the established acceptance range, it 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. Performance characteristics for ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control have been established only for HPV mRNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

ACCURUN 381 HPV Type 16 and 18 mRNA Positive 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. 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].

Note that because HPV 16 and HPV 18 are both high risk types, vial A381-01 and vial A381-02 are expected to give similar results on those assays that detect high risk HPV. The two vials are expected to give distinct results on HPV genotyping assays.

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* diagnostic assay procedures for the purposes of monitoring assay performance. ACCURUN 381 HPV Type 16 and 18 mRNA Positive Control is manufactured from human cell lines bearing HPV 16 or HPV 18 integrated into the cellular genome mixed with uninfected cells and diluted in a buffered methanol 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.

REFERENCES

1. 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.
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 CFR268.40; 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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