ACCURUN® 378
SERIES 5000

HPV DNA
Positive Control

CE

EC REP

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About this package insert

Thank you for your interest in this ACCURUN product.

This package insert consists of two pages.

The first page contains the product name and an explanation of the symbols used on the labeling.

The second page contains the complete package insert text.

If the package insert you view or print does not contain two pages, or if you experience any problems, please email us at info@seracare.com. By phone: US customers call 800.676.1881; International customers call collect 508.634.3359.

A printed package insert will be sent to you upon request.

SeraCare LIFE SCIENCES

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Explanation of symbols used in SeraCare product labeling


Upper limit of temperature


Temperature limitation


Highly flammable

IVD
In Vitro Diagnostic Medical Device


Biological risks


Use By


"Caution, consult accompanying documents"


Toxic by inhalation, in contact with skin and if swallowed

CONTROL –
Negative control

REF
Catalogue number

EC REP
Authorized Representative in the European Community

CONTROL +
Positive control

LOT
Batch code

US

ACCURUN® 378
SERIES 5000
HPV DNA Positive Control

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

NAME AND INTENDED USE

ACCURUN controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN® 378 HPV DNA Positive Control Series 5000 has been formulated for use with *in vitro* diagnostic test methods that detect HPV DNA 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 378 HPV DNA Positive Control has been designed for use with *in vitro* diagnostic assay procedures for the purpose of monitoring test performance. ACCURUN 378 HPV DNA Positive Control is manufactured from cultured human cells containing full-length human papillomavirus (HPV) episomal DNA (transfected cells) and mixed with non-infected cells from tissue culture. The transfected cells contain full length HPV type 16 mixed with non-infected cells preserved in a buffered methanol solution[2]. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

REAGENTS

Cat. No. A378-5030	20 vials, 4 mL per vial
Cat. No. A378-5045-T	1 vial, 4 mL per vial (trial size)

ACCURUN 378 HPV DNA Positive Control contains buffered methanol[2].

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 378 HPV DNA Positive Control is manufactured from HPV type 16 transfected human cells and other non-infected 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[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 378 must be disposed of by following RCRA ID#D001 guidelines for ignitable waste[4]. Keep ACCURUN 378 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 378 at 2-8°C until use. Once opened, ACCURUN 378 should not be reused. Store vials upright to prevent leakage.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

ACCURUN 378 HPV DNA 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 ACCURUN 378 and such solutions should be discarded.

PROCEDURE

Materials Provided

ACCURUN 378 HPV DNA Positive Control is manufactured from HPV type 16 transfected human cells and other non-infected 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 controls to come to room temperature before use. Mix by hand 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 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 378 HPV DNA 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 378 HPV DNA Positive Control. When results for ACCURUN 378 HPV DNA Positive 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 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 378 HPV DNA Positive 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 378 HPV DNA Positive 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[5].

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN controls have been designed for use with *in vitro* diagnostic assay procedures for purposes of monitoring assay performance. ACCURUN 378 HPV DNA Positive Control is manufactured from transfected human cells mixed with non-infected 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. Cytyc PreservCyt® Solution Package Insert Part number 050001, Rev D. Cytyc Corporation, 85 Swanson Road, Boxborough, MA 01719.
3. CDC recommendations for prevention of HIV transmission in health care settings. MMWR 36 (supp. 2), 1987.
4. Treatment standards for hazardous waste; 40 CFR 268.40; Subpart D. D001: Ignitable characteristics of waste.
5. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Second Edition. NCCLS document C24-A2, 1999.

For assistance, contact SeraCare Technical Support at 1.508.244.6400.

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