ACCURUN® TV/MG

Positive Molecular Control Kit

CE 2797

EC REP

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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

Single Use

Importer

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

ACCURUN® TV/MG Positive Molecular Control Kit

NAME AND INTENDED USE

ACCURUN® TV/MG Positive Molecular Control Kits are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. ACCURUN TV/MG Positive Molecular Controls have been formulated for use with *in vitro* diagnostic test kits for the detection of *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) in molecular assays. ACCURUN controls do not have quantitative assigned values. *For professional laboratory use only.*

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 enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, 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 low-reactive samples as independent controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

ACCURUN TV/MG Positive Molecular Controls have been designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN TV/MG Positive Molecular Control are manufactured from human urine. ACCURUN TV/MG Positive Molecular Control do not have assigned values. Examples of assay(s) with which this control may be compatible are listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

REAGENTS

Item No. 2020-0164 10 vials, 2.5 mL per vial

This positive control contains human urine, stabilizers including sodium azide, and cultured *T. vaginalis and M. genitalium* microorganisms.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

CAUTION: Handle ACCURUN TV/MG Positive Molecular Controls and all human urine products as though capable of transmitting infectious agents. ACCURUN TV/MG Positive Molecular Controls are manufactured from urine tested and found negative for HIV-1, HCV, and HBV using FDA approved methods.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN TV/MG Positive Molecular Controls and human urine[2]. Do not pipette by mouth; do not 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. Additional safety information can be found in the product Safety Data Sheet (SDS) found on the company website.

Handling Precautions

Do not use ACCURUN TV/MG Positive Molecular Controls beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store ACCURUN TV/MG Positive Molecular Controls frozen at -20 °C. Once thawed, unopened vials of ACCURUN TV/MG Positive Molecular Controls can be stored at 2- 8 °C for up to 20 days. Multiple freeze-thaw cycles are not recommended and may have variable adverse effects upon test results. Vials are intended for single use only.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN TV/MG Positive Molecular Controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN TV/MG Positive Molecular Controls are manufactured from human urine and cultured *T. vaginalis* and *M. genitalium* microorganisms.

Materials Required but not Provided

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

Instructions for Use

If frozen, allow controls to thaw and reach room temperature prior to use. Mix contents thoroughly by vortexing prior to use. ACCURUN TV/MG Positive Molecular Controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown urine specimens. ACCURUN TV/MG Positive Molecular Controls must NOT be substituted for the positive and negative control reagents provided with test kits.

Quality Control

Since ACCURUN TV/MG Positive Molecular Controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN TV/MG Positive Molecular Control Kit with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN TV/MG Positive Molecular Controls may vary with different manufacturers' tests and different test kit lots. Each laboratory must establish its own range of acceptable values for ACCURUN TV/MG Positive Molecular Controls with the particular test kits being used. When results for ACCURUN TV/MG Positive Molecular Controls are outside the established acceptable range of values, 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 TV/MG POSITIVE MOLECULAR 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 TV/MG Positive Molecular Controls are qualitative, not automated, and are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

ACCURUN TV/MG POSITIVE MOLECULAR CONTROL KIT DO NOT HAVE ASSIGNED VALUES.

This positive control has been formulated to produce positive reactivity in those manufacturers' assays listed in Table 1. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values for each analyte. 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[3].

SPECIFIC PERFORMANCE CHARACTERISTICS

ACCURUN TV/MG Positive Molecular Controls have been designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN TV/MG Positive Molecular Controls are manufactured from human urine and cultured microorganisms. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different reagent 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. Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

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. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Fourth Edition. CLSI document C24, 2016.

Table 1. This product is tested using the following assays:

Marker	Manufacturer / Product Name	Result
Trichomonas Vaginalis (TV)	Abbott Alinity m STI Assay Hologic Aptima® Trichomonas vaginalis Assay (Panther® System)	Positive
Mycoplasma Genitalium (MG)	Abbott Alinity m STI Assay Hologic Aptima Mycoplasma genitalium Assay	Positive

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

Any serious incident that has occurred in relation to the device shall be reported to LGC Clinical Diagnostics Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date	Description of Change
September 2024	Initial release
November 2024	Storage Instructions section - Updated to change 2-8°C storage from 30 days to 20 days.

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