ACCURUN® Babesia

Positive Molecular Control Kit

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Explanation of symbols used in LGC Clinical Diagnostics product labeling

Upper limit of temperature

Temperature limitation

In Vitro Diagnostic Medical Device

Biological risks

Use By

Consult instructions for use

Negative control

Catalogue number

Manufacturer

Positive control

Batch code

Toxic by inhalation, in contact with skin and if swallowed

Control

Highly Flammable

Health Hazard

Single Use

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

ACCURUN® Babesia Positive Molecular Control Kit

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 Babesia Positive Molecular Control Kits have been formulated for use with *in vitro* diagnostic test kits for the detection of Babesia microti organisms.

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 Babesia Positive Molecular Controls have been designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN Babesia Positive Controls are manufactured from cultured Babesia microti organisms in a whole blood-based matrix. ACCURUN Babesia Positive Molecular Controls do not have assigned values. Specific levels of reactivity will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

REAGENTS

Item No. 2020-0155	5 x 2.0 mL vials positive control 5 x 2.0 mL vials lysis buffer 5 x 4.0 mL vials diluent

This positive control contains human whole blood and a cryopreservative.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

CAUTION: Handle ACCURUN Babesia Positive Molecular Controls and all human blood products as though capable of transmitting infectious agents. ACCURUN Babesia Positive Molecular Controls are manufactured from human whole blood containing a cryopreservative.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN Babesia Positive Molecular Controls and human blood[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.

Handling Precautions

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

STORAGE INSTRUCTIONS

Store ACCURUN Babesia Positive Molecular Control Kit at -20°C or lower until use. Once opened, an individual vial of ACCURUN Babesia Positive Molecular Control could be stored at 2-8°C for up to 30 days. Multiple freeze-thaw cycles are not recommended, and may have variable adverse effects upon test results. To prevent leakage, store vials upright.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of ACCURUN Babesia Positive Molecular Controls, and product with altered appearance should be discarded.

PROCEDURE

Materials Provided

ACCURUN Babesia Positive Molecular Controls are manufactured from cultured Babesia microti and human whole blood. Lysis buffer and diluent are also provided in the ACCURUN Babesia Positive Molecular Control Kit.

Materials Required but not Provided

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

Instructions for Use

The lysis buffer vials provided inside the kit should only be added to the controls when the test being performed requires starting materials that are lysed. If lysed blood is required, mix lysis buffer and Babesia positive control in equal volumes and then load lysed sample onto the test system. Alternatively, lysis buffer provided by the test kit manufacturer can also be used, following the test kit manufacturer's instructions for unknown patient samples. If the test being performed requires unlysed whole blood as the starting material, then the lysis buffer included in the ACCURUN kit is unneeded and may be discarded. Optional diluent can be used to dilute the positive control to achieve a lower level of detection if desired.

Mix the contents of the vials gently. Allow the controls to reach room temperature prior to use, then return controls to refrigerated storage immediately after use. ACCURUN Babesia Positive Molecular Controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN Babesia Positive Molecular Controls must NOT be substituted for the positive and negative control reagents provided with licensed test kits.

Quality Control

Since ACCURUN Babesia Positive Molecular Controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN Babesia 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 Babesia 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 Babesia Positive Molecular Controls with the particular test kits being used. Acceptable limits should be established using consistent procedures for control testing, as results using alternate lysis buffers may vary. When results for ACCURUN Babesia Positive Molecular Controls are outside the established acceptable range of values, it may be an indication of unsatisfactory test performance. Possible sources of error are: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

LIMITATIONS OF THE PROCEDURE

ACCURUN BABESIA 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 Babesia Positive Molecular Controls 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 BABESIA POSITIVE MOLECULAR CONTROLS DO NOT HAVE ASSIGNED VALUES.

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 Babesia Positive Molecular Controls have been designed for use with in vitro assay procedures for purposes of monitoring assay performance. ACCURUN Babesia Positive Molecular Controls are manufactured from cultured Babesia microti and human whole blood. ACCURUN Babesia Positive Molecular Controls do not have assigned values. 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.

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.

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.

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