ACCURUN® 155 SERIES 5000

Anti-Treponema (Syphilis) 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® 155 SERIES 5000 Anti-Treponema (Syphilis) Positive Control

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® 155 Anti–Treponema (Syphilis) Positive Control has been formulated for use with *in vitro* diagnostic test kits for the qualitative determination of IgG antibodies to *Treponema pallidum* (Syphilis), including assay procedures for blood screening, and for the diagnosis and monitoring of patients infected with T. pallidum. A positive control for tests for Reagin is available separately from LGC Clinical Diagnostics. *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 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 155 Syphilis Positive Control has been designed for use with *in vitro* assay procedures for purposes of monitoring test performance. ACCURUN 155 Syphilis Positive Control is manufactured from human serum or plasma reactive for anti-Treponema and nonreactive for HBsAg and for antibodies to HIV 1 and 2, HTLV I and II, and HCV. ACCURUN controls do not have assigned values. This 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 lot numbers, and different laboratories.

REAGENTS

Item No. 2015-0093	3 vials, 2.0 mL per vial
Item No. 2015-0092	12 vials, 3.5 mL per vial

This control contains human serum or plasma, stabilizers (EDTA, buffering agents), and 0.1% ProClin® (5-chloro-2-methyl-4-isothiazolin-3-one & 2-methyl-4-isothiazolin-3-one) as preservative.

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 155 Syphilis Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV with current FDA required tests.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling ACCURUN and human blood[2]. Disposable gloves should be worn while handling reagents, controls or specimens. 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. After handling reagents, controls or specimens, wash hands thoroughly.

Handling Precautions

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

STORAGE INSTRUCTIONS

Store ACCURUN 155 Syphilis Positive Control at 2-8°C. Once opened, ACCURUN 155 Syphilis Positive Control should be stored at 2-8°C and discarded after 60 days. After opening, record the date opened and the expiration date on the vial. 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 controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

ACCURUN 155 Syphilis Positive Control is manufactured from human serum or plasma reactive for anti-Treponema and nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV. See REAGENTS for a list of package sizes.

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 reach room temperature prior to use, then return controls to refrigerated storage immediately after use. Mix the contents of the vials by gentle inversion. ACCURUN controls should be included in a test run using exactly the same procedure provided by the manufacturer for unknown specimens. ACCURUN controls must NOT be substituted for the positive and negative control reagents provided with manufactured test kits. Acceptance ranges should be established each time a new lot of ACCURUN 155 Syphilis Positive Control is used. Do not mix different lots of ACCURUN 155.

Quality Control

Since ACCURUN controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of ACCURUN control with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of ACCURUN 155 Syphilis Positive Control may vary with different manufacturers' tests and different test kit lots. Each laboratory must establish its own range of acceptable values for ACCURUN 155 Syphilis Positive Control with the particular test kits being used. When results for ACCURUN 155 Syphilis Positive Control are outside the established acceptable range of values, it may be an indication of unsatisfactory test performance. Possible sources of discrepancy are: deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, or cross-contamination of the ACCURUN control with high titer specimens or nonreactive specimens.

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. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. ACCURUN 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 155 Syphilis Positive Control DOES NOT HAVE AN ASSIGNED VALUE. 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 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 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 controls have been designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. ACCURUN 155 Syphilis Positive Control is manufactured from human serum or plasma nonreactive for HBsAg and antibodies to HIV 1 and 2, HTLV I and II, and HCV. ACCURUN controls 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 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–Second Edition. NCCLS document C24-A2, 1999.

TABLE 1. ACCURUN 155 Syphilis Positive Control Series 5000 is reactive in the following manufacturers' tests (product #):

1. Trinity Biotech USA, Jamestown, NY 14702	CAPTIA™ Syphilis-G EIA (M411)
2. Olympus America, Inc., Melville, NY 11747	PK™TP System (PH3000)
3. Zeus Scientific, Inc., Raritan, NJ 08869	FTA-ABS Test System (7000)

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

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