AccuPlex™ SARS-CoV-2 Full Genome w/cRNA

Positive Control 1500 cp/mL Kit

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

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

AccuPlex™ SARS-CoV-2 Full Genome w/cRNA

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NAME AND INTENDED USE

AccuPlex™ SARS-CoV-2 Full Genome w/cRNA Positive Control 1500 cp/mL Kit is formulated for use with *in vitro* diagnostic test methods that detect the SARS-CoV-2 virus, the causative agent of COVID-19 disease. The controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. AccuPlex controls contain non-replicative recombinant viruses that are intended to assess the performance of the full process of a molecular test. AccuPlex can be used to evaluate test proficiency and accuracy through the full process because they are encapsulated viruses which require extraction and amplification. *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

AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit has been designed for use with in vitro assay procedures for purposes of monitoring test performance. This product contains recombinant Alphavirus. There are 81 vials of positive controls that contain recombinant virus particles with sequences comprising the entire SARS-CoV-2 genome. The sequences are based on the Genbank accession number NC_045512.2. This material must go through extraction, similar to the patient sample.

AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control does not have assigned values. The control has been formulated at a targeted formulation of 1500 copies/mL, as measured using reverse transcription digital PCR, to perform as a positive control in assays that detect SARS-CoV-2 RNA. Representative data are presented for reference only in Table 1. Specific performance will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

REAGENTS

Item No. 0505-0220 — 81 x 0.3 ml vials

The product is formulated in viral transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents, and human plasma proteins.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

CAUTION: The recombinant viruses used to produce the AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control are replication defective and heat-treated. However, handle AccuPlex products and all human blood products as though they can transmit infectious agents.

Safety Precautions

Use the Centers for Disease Control (CDC) recommended universal precautions for handling AccuPlex controls [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 AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

Store the AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control refrigerated at 2-8°C. Do not expose to multiple freeze thaw cycles. Vials are single-use only. Discard after initial use. To prevent leakage, store vials upright.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of AccuPlex controls. Solutions that are visibly turbid should be discarded.

PROCEDURE

Materials Provided

AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit is manufactured from recombinant virus particles in viral transport media. See REAGENTS for package size.

Materials Required but not Provided

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

Instructions for Use

Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous suspension. AccuPlex SARS-CoV-2 molecular controls should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex SARS-CoV-2 molecular controls must go through an extraction process prior to detection by PCR. Process the product according to the instructions for unknown samples provided by the test kit or the laboratory's standard operating procedures. AccuPlex SARS-CoV-2 molecular controls must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

Quality Control

Since AccuPlex SARS-CoV-2 molecular controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity for the AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control may vary with different manufacturers' tests and different test kit lots. This product contains a targeted formulation of 1500 copies/mL as measured using reverse transcription digital PCR. Each batch is tested using 2019-nCoV primers/probes described in the US CDC Assay publication and using testing protocols similar to that described in CDC published instructions for use [3]. Positive controls give positive results on these assays. Note that the positive control may contain traces of RNase P and therefore generate a positive RNase P result due to the presence of a human plasma component in the product matrix; it is not designed or intended to be used as an RNase P control.

If AccuPlex SARS-CoV-2 molecular controls do not perform as expected, this 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

AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit 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. AccuPlex SARS-CoV-2 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. Performance characteristics for AccuPlex SARS-CoV-2 molecular controls have been established only for amplified nucleic acid tests for RNA only. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS

AccuPlex SARS-CoV-2 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. 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, as appropriate. 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].

SPECIFIC PERFORMANCE CHARACTERISTICS

AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit has been designed for use with *in vitro* assay procedures for purposes of monitoring assay performance. The controls are intended for use with nucleic acid-based detection assays only. AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control Kit is manufactured from recombinant virus particles in viral transport media. AccuPlex SARS-CoV-2 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. CDC 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel Instructions for use. CDC-006-00019 Revision: 01. Effective 2/4/2020.
4. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Second Edition. NCCLS document C24-A2, 1999.

Table 1. Representative data for AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control 1500 cp/mL Kit. For reference only.

Assay Manufacturer/Test Name	Product Component	Result
Laboratory Developed Test using US CDC 2019 nCoV Real Time PCR Primers and Probes	AccuPlex SARS-CoV-2 Full Genome w/cRNA Positive Control 1500 cp/mL	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.

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