AccuPlex™ rEbola

GP/NP Reference Material

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

AccuPlex™ rEbola GP/NP Reference Material

NAME AND INTENDED USE

AccuPlex™ rEbola GP/NP Reference Material is formulated for use with test methods that detect the Ebola 2014 outbreak strain (EBOV, Zaire ebolavirus 2014). AccuPlex virus products are 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

Diagnostic developers and analysts rely on positive disease state materials that can effectively challenge all elements of an assay from sample preparation through amplification and detection. Valuable process controls and reference materials will mimic natural samples and include encapsulated virus with lipid bilayers.

A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent controls and reference materials may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

AccuPlex rEbola GP/NP Reference Material is designed for use with assay procedures that test for Ebola virus (2014 Outbreak strain) genomic RNA and target the nucleoprotein (NP, base pairs 61-840 and 1080-1860 of the NP gene), envelope glycoprotein (GP, base pairs 151-2100 of the GP gene) or VP24 (base pairs 121-670 of the VP24 gene) genes. The product is not for use with Ebola tests which target the L polymerase gene or sequences outside of the NP, GP and VP24 genes. Truncated RNA sequences from these genes (Genbank accession number KJ660348.2) are packaged into a specially modified recombinant viral vector and diluted in defibrinated human plasma. The product is ready-to-use for extraction and detection via amplified nucleic acid tests.

AccuPlex rEbola GP/NP utilizes an RNA containing enveloped Alpha virus that has been developed as a viral vector over many years[2]. The viral genome contains a single-stranded positive sense RNA. The genes coding for the viral structural proteins can be deleted and replaced with "target" sequences of interest. In AccuPlex rEbola GP/NP Reference Material, Alpha virus structural genes are replaced with Ebola NP, GP and VP24 sequences. The resulting recombinant viral particles are efficiently packaged in host cells, but lack the genes required to produce new viral particles, and are therefore replication defective.

REAGENTS

Item No. 0505-0001 5 vials, 0.25 mL per vial

AccuPlex rEbola GP/NP Reference Material is formulated in defibrinated human plasma, tested and found negative for common bloodborne pathogens (Negative for the presence of antibody to HIV1/2, antibody to HCV, antibody to HBc, antibody to HTLV I/II, HIV RNA, HCV RNA, HBV DNA and HBsAg). The buffer also includes purified human genomic DNA and 0.09% sodium azide.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

CAUTION: The recombinant viruses used to produce the AccuPlex rEbola GP/NP Reference Material are replication defective and heat-treated. However, handle AccuPlex products and all human blood products as though capable of transmitting infectious agents.

Although the recombinant viruses bear sequences from Ebola, they were designed to ensure that no functional Ebola proteins are produced. The GP, NP and VP24 genes are severely truncated and contain engineered stop codons. The Alpha virus vector system is replication defective due to deletion/replacement of structural genes. Additionally, as a further safety precaution, the recombinant viruses are heat-treated for duration and at a temperature which has been shown to inactivate other RNA based viruses[3].

Safety Precautions

Use Center for Disease Control and Prevention (CDC) recommended universal precautions for handling AccuPlex and human specimens[4]. 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 and materials used in testing as though they contain infectious agents.

Handling Precautions

Do not use AccuPlex rEbola GP/NP Reference Material beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store AccuPlex rEbola GP/NP Reference Material at 2-8°C until use. Once opened, an individual vial of AccuPlex rEbola GP/NP Reference Material should not be reused.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

AccuPlex rEbola GP/NP Reference Material is a mixture of recombinant Alpha viruses that bear Ebola NP, GP and VP24 sequences suspended in defibrinated human plasma. It will appear as a yellow to amber liquid. Alterations in this appearance or visible microbial growth may indicate instability or deterioration of the product and vials should be discarded.

PROCEDURE

Materials Provided

AccuPlex rEbola GP/NP Reference Material is manufactured using recombinant Alpha viruses, defibrinated human plasma, purified human genomic DNA and 0.09% sodium azide.

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 reference materials should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. For assays which require swab absorption of test samples, transfer the entire contents of the vial directly to the sample reagent. AccuPlex rEbola GP/NP Reference Materials 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 reference materials must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

Quality Control

Since AccuPlex rEbola GP/NP Reference Material does not have assigned values, it is recommended that each laboratory qualify the use of each lot of AccuPlex rEbola GP/NP Reference Material with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of AccuPlex rEbola GP/NP Reference Material may vary with different types of tests and different test kit lots. Since the reference material does not have an assigned value, the analyst must establish a range for each lot of AccuPlex rEbola GP/NP Reference Material. When results for the product are outside of the established acceptance range, it may indicate 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

AccuPlex Reference Materials MUST NOT BE SUBSTITUTED FOR THE 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 materials are not calibrators and should not be used for assay calibration. Performance characteristics for AccuPlex rEbola GP/NP Reference Material have been established only for amplified nucleic acid tests for genomic RNA (NP, GP and VP24 genes). Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

AccuPlex rEbola GP/NP Reference Material DOES 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. 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 20 days[5].

SPECIFIC PERFORMANCE CHARACTERISTICS

AccuPlex products have been designed for use with test procedures for the purposes of assessing assay performance. AccuPlex rEbola GP/NP Reference Materials are manufactured from recombinant viruses that bear Ebola gene sequences. AccuPlex products do not have assigned values. 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 procedures designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin. Chem. 43:9 1618-1621, 1997.
2. Schlesinger S. 2000. Alphavirus expression vectors. Adv Virus Res. 55:565-77.
3. Sofer G. 2003. Virus Inactivation in the 1990s—and into the 21st Century Part 4, Culture Media, Biotechnology Products, and Vaccines. BioPharm International. January: pp50-57.
4. 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.
5. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Second Edition. NCCLS document C24-A2, 1999.

Table 1. Typical Data for AccuPlex rEbola GP/NP Reference Material.

Content	Expected Results
AccuPlex rEbola GP/NP Reference Material	Positive and/or detected

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