AccuPlex™

Zika Reference Material

Package Insert

PLEASE NOTE:
THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

AccuPlex™ Zika Reference Material is formulated for use with nucleic acid test methods that detect the ZIKV 2007 strain. AccuPlex virus products are non-replicative recombinant viruses that are intended to assess the performance of the full process of a molecular test. AccuPlex Zika Reference Material can be used to evaluate test proficiency and accuracy through the full process because they are encapsulated viruses which require extraction and amplification. *For Research Use only. Not for use in diagnostic procedures.*

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 reference materials may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity[1].

PRINCIPLES OF THE PROCEDURE

AccuPlex Zika Reference Material is designed for use with assay procedures that test for Zika virus (2007 outbreak strain) viral RNA. The entire genomic RNA sequence from ZIKV 2007 strain (Genbank Accession number: EU545988.1) is packaged into specially modified recombinant viral vectors and diluted in defibrinated human plasma. The product is ready-to-use for extraction and detection via amplified nucleic acid tests.

AccuPlex Zika Reference Material utilizes an RNA containing enveloped Alpha virus that has been developed as a viral vector over many years[2]. The viral genome contains single-stranded positive-strand sense RNA. The genes coding for the viral structural proteins can be deleted and replaced with “target” sequences of interest. In AccuPlex Zika Reference Material, Alpha virus structural genes are replaced with Zika 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. 0505-0029 1 vial, 0.25 mL per vial

AccuPlex Zika 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 matrix also includes purified human genomic DNA and 0.09% sodium azide.

WARNINGS AND PRECAUTIONS

For Research Use only. Not for use in diagnostic procedures.
CAUTION: The recombinant viruses used to produce the AccuPlex Zika Reference Material are replication defective and heat-treated. However, handle AccuPlex products and all human blood products as though they are capable of transmitting infectious agents.

As a safety precaution, the Zika genome is separated into multiple viral vectors so that each recombinant virus produced bears only a portion of the genome. 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 a duration and at a temperature which has been shown to inactivate other RNA based viruses[3].

Safety Precautions

Use Centers for Disease Control (CDC) recommended universal precautions for handling AccuPlex Zika Reference Material 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 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 Zika Reference Material beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store AccuPlex Zika Reference Material at 2-8 ºC until use. Once opened, an individual vial of AccuPlex Zika Reference Material should not be reused.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

AccuPlex Zika Reference Material is a mixture of recombinant Alpha viruses that bear entire Zika 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 Zika Reference Material is manufactured using recombinant Alpha viruses, defibrinated human plasma, purified human genomic DNA and 0.09% sodium azide; 0.25 mL is provided per tube.

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 Zika Reference Material should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex Zika 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 Zika Reference Material must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

Quality Control

AccuPlex Zika Reference Material does not have assigned values. It is recommended that each laboratory qualify the use of each lot of AccuPlex Zika Reference Material with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS

Levels of reactivity of AccuPlex Zika 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 Zika 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.

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LIMITATIONS OF THE PROCEDURE

AccuPlex Zika 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 Zika Reference Material have been established only for amplified nucleic acid tests for genomic RNA. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

AccuPlex Zika 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 Zika Reference Materials are manufactured from recombinant viruses that bear Zika genome 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 procedure 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.

For assistance, contact SeraCare Technical Support at 508.244.6400