Explanation of symbols used in SeraCare product labeling

- **Upper limit of temperature**
- **Temperature limitation**
- **Biological risks**
- **Use By**
- **Negative control**
- **Catalogue number**
- **Positive control**
- **Batch code**
- **Control**
- **Manufacturer**
- **Highly Flammable**
- **Toxic by inhalation, in contact with skin and if swallowed**
- **Health Hazard**
- **Authorized Representative in the European Community**
- **In Vitro Diagnostic Medical Device**
- **Consult instructions for use**
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 virus (2014 Outbreak strain) genomic RNA and target the nucleoprotein (NP, base pairs 61-670 of the GP gene), envelope glycoprotein (GP, base pairs 151-2105 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 KJ603482.2) 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 Reference Material utilizes an RNA containing enveloped Alpha virus that has been developed as a viral vector over many years². 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. 1050-0001
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 HIV 1/2, antibody to HCV, antibody to HBV, antibody to HTLV I/II, HIV RNA, HCV RNA, HBV DNA and HBsAg). The buffer also includes purified human genomic DNA and 0.05% 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 products 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 viruses³.

PROCEDURE

Materials Provided
AccuPlex® rEbola GP/NP Reference Material is manufactured using recombinant Alpha viruses, defibrinated human plasma, purified human genomic DNA and 0.05% 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 calibrate 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 unsusatisfactory 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 2 rows over a period of 20 days⁴.

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


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

<table>
<thead>
<tr>
<th>Content</th>
<th>Expected Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>AccuPlex® rEbola GP/NP Reference Material</td>
<td>Positive and/or detected</td>
</tr>
</tbody>
</table>

For assistance, contact SeraCare Technical Support at +1 508.244.6400.