AccuPlex™ rEbola
GP/NP Reference Material

Explanation of symbols used in SeraCare product labeling

- Upper limit of temperature
- Temperature limitation
- Authorized Representative in the European Community

- Biological risks
- Use By
- In Vitro Diagnostic Medical Device

- Negative control
- Catalogue number
- Consult instructions for use

- Positive control
- Batch code
- Manufacturer

- 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 virus (2014 Outbreak strain) genomic RNA and target the nucleoprotein (NP, base pairs 61-206 and 1080-1209 of the NP gene), envelope glycoprotein (GP, base pairs 151-2103 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 KJ603048.2) are packed 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.

PRINCIPLES OF THE PROCEDURE
AccuPlex rEbola GP/NP Reference Material is designed for use with assay procedures that test for Ebola virus genomic RNA and target the nucleoprotein (NP, base pairs 61-206 and 1080-1209 of the NP gene), envelope glycoprotein (GP, base pairs 151-2103 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 KJ603048.2) are packed 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.

PROEDURE
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 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 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.

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>
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<tbody>
<tr>
<td>AccuPlex rEbola GP/NP Reference Material</td>
<td>Positive and/or detected</td>
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For assistance, contact SeraCare Technical Support at +1 508.244.6400.