Explanation of symbols used in LGC Clinical Diagnostics 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 (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.

PROCEDURE
Materials Provided
AccuPlex™ rEbola GP/NP Reference Material is manufactured using recombinant Alpha viruses, dehydrated 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
Refer to instructions supplied by manufacturers of the test kits to be used. 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
Although recombinant viruses bear sequences from Ebola, they were designed to ensure that no infectious agents are present in AccuPlex products. AccuPlex products have been designed for use with test procedures for the purposes of assessing assay performance. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established for 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 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.

LESLIE M. LAYTON, SC. D.
Director, Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Blood Product Branch

LIMITATIONS OF THE PROCEDURE
AccuPlex Reference Materials must NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

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>
</tr>
</thead>
<tbody>
<tr>
<td>AccuPlex™ rEbola GP/NP Reference Material</td>
<td>Positive and/or detected</td>
</tr>
</tbody>
</table>

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400.