AccuPlex™ SARS-CoV-2, Flu A/B and RSV
Molecular Controls Kit

Explanation of symbols used in LGC SeraCare product labeling

- **Upper limit of temperature**
- **Temperature limitation**
- **Biological risks**
- **Negative control**
- **Positive control**
- **Control**
- **Authorized Representative in the European Community**
- **In Vitro Diagnostic Medical Device**
- **Consult instructions for use**
- **Manufacturer**
- **Catalogue number**
- **Batch code**
- **Single Use**
- **Use By**
NAME AND INTENDED USE
AccuPlex™ SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit is intended to be used as positive and negative controls to monitor laboratory testing precision and detect errors in laboratory testing procedures. The controls are formulated for use with in vitro diagnostic test methods that detect SARS-CoV-2, Flu A/B and RSV. The controls are intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. AccuPlex controls contain non-replicative recombinant viruses 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. AccuPlex controls do not have quantitative assigned values. For professional laboratory use only.

SUMMARY
Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits, and operator variation, and can assist in identifying increases in random or systematic error. A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of in vitro reagents as independent controls may provide valuable information concerning laboratory proficiency and kit lot variation that may affect assay sensitivity.

PRINCIPLES OF THE PROCEDURE
AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit has been designed for use with in vitro assays for purposes of monitoring test performance. The product contains recombinant Alphavirus. There are 5 vials of positive reference material (red caps) which contain recombinant virus particles with the following sequence coverage:

<table>
<thead>
<tr>
<th>Virus</th>
<th>Genbank Accession</th>
<th>Regions Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu A</td>
<td>KU933490</td>
<td>Full Genome</td>
</tr>
<tr>
<td>Flu B</td>
<td>CY236901.1-CY236908.1</td>
<td>Full Genome</td>
</tr>
<tr>
<td>RSV</td>
<td>NC_001803</td>
<td>1,4380</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8460, 15191</td>
</tr>
<tr>
<td>SARS-CoV-2</td>
<td>NC_045512.2</td>
<td>Full Genome</td>
</tr>
</tbody>
</table>

There are also 5 vials of negative controls (clear caps) which contain recombinant virus particles with sequences from human RNAse P gene (RP). These sequences are based on GenBank accession NC_001800 to 11. The material must go through extraction, similar to the patient sample.

AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit do not have assigned values. The controls are formulated at a targeted concentration of 5000 copies/mL as measured using reverse transcription digital PCR. Possible sources of error include deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

REAGENTS

- Item No. 05050262:
  - Positive: 0505-0262 5 x 1.5 ml vials
  - Negative: 0505-0263 5 x 1.5 ml vials

The product is formulated in viral transport media that consists of Tri-buffered saline, with added glycero, anti-microbial agents, and human plasma proteins.

WARNINGS AND PRECAUTIONS
For In Vitro Diagnostic Use:
CAUTION: The recombinant viruses used to produce the AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit are replication defective and heat treated. However, handle AccuPlex products and all human blood products as though they can transmit infectious agents.

Safety Precautions
Use the Centers for Disease Control (CDC) recommended universal precautions for handling AccuPlex controls. Do not pipette by mouth; do not 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, controls and materials used in testing as though they contain infectious agents. Additional safety information can be found in the product Safety Data Sheet (SDS) found on the company website.

Handling Precautions
Do not use AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit beyond the expiration date. Avoid microbial contamination of the controls when opening and disposing the vials.

STORAGE INSTRUCTIONS
Store the AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit refrigerated at 2-8°C or frozen at -20°C. If stored at -20°C, once thawed maintain at 2-8°C. Do not expose to multiple freeze-thaw cycles. Each vial can be used up to 10 times within 60 days of opening. To prevent leakage, store vials upright.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
Alterations in physical appearance may indicate instability or deterioration of AccuPlex controls. Solutions that are visibly turbid should be discarded.

PROCEDURE
Materials Provided
AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit is manufactured from recombinant virus particles in viral transport media. See REAGENTS for package size.

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 SARS-CoV-2, Flu A/B and RSV molecular controls should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls must NOT be substituted for the positive and negative control reagents provided with the manufactured test kits.

Quality Control
Since AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS
Levels of reactivity for the AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls may vary with different manufacturers' tests and different lot kits. The product contains a targeted formation of 5000 copies/mL as measured using reverse transcription digital PCR. Positive controls are intended to give positive results, while negative controls give negative or not detected results. Note that the positive controls may contain traces of RNAse P and therefore generate a positive RNAse P result due to the presence of a human plasma component in the product matrix; it is not designed or intended to be used as an RNAse P control.

If AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls do not perform as expected, this may be an indication of 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 SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit MUST NOT BE SUBSTITUTED FOR THE POSITIVE AND NEGATIVE 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 SARS-CoV-2, Flu A/B and RSV molecular controls are qualitative, not automated, and must be used for calibration and monitoring test performance only. Performance characteristics for AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls have been established only for amplified nucleic acid tests for RNA only. Adverse shipping and/or storage conditions or use of outdated controls may produce erroneous results.

EXPECTED RESULTS
AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls DO 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, as appropriate. 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 30 days.

SPECIFIC PERFORMANCE CHARACTERISTICS
AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit has been designed for use with in vitro assay procedures for purposes of monitoring assay performance. The controls are intended for use with nucleic acid-based detection assays only. AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit is manufactured from recombinant virus particles in viral transport media. AccuPlex SARS-CoV-2, Flu A/B and RSV molecular controls do 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. Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

REFERENCES

Table 1. AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls Kit is tested at release using the following manufacturer's assays.

<table>
<thead>
<tr>
<th>Assay Manufacturer/Test Name</th>
<th>Product Component</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cepheid Xpert® Assay SARS-CoV-2/Flu/RSV Kit</td>
<td>AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls: Positive Vial</td>
<td>Positive</td>
</tr>
<tr>
<td>AccuPlex SARS-CoV-2, Flu A/B and RSV Molecular Controls: Negative Vial</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

For assistance, contact LGC SeraCare Technical Support at +1 508.244.6400. Any serious incident that has occurred in relation to the device shall be reported to LGC SeraCare Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date: September 2021
Description of Change: Initial release