AccuPlex™ Human RNase P
Negative Control Kit

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**

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AccuPlex™ Human RNase P Negative Control Kit

NAME AND INTENDED USE
AccuPlex™ Human RNase P Negative Control Kit is formulated for use with in vitro diagnostic test methods that detect the SARS-CoV-2 virus, the causative agent of COVID-19 disease. The control is intended to estimate laboratory testing precision and can be used to detect errors in laboratory testing procedures. AccuPlex controls contain 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.

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 performance, hit-to-hit performance of test kits, and operator variation, and 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 non-reactive samples as independent controls may provide valuable information concerning laboratory proficiency and hit-to-hit variation that may affect assay sensitivity.  

PRINCIPLES OF THE PROCEDURE
AccuPlex Human RNase P Negative Control has been designed for use with in vitro assay procedures for purposes of monitoring test performance. This product contains recombinant AlphaVirus. There are 81 vials of negative controls that contain recombinant virus particles with sequences comprising portions of the Human RNase P gene. This material must go through extraction, similar to the patient sample. AccuPlex Human RNase P Negative Control does not have assigned values. The control has been formulated at a targeted formulation of 5000 copies/mL, as measured using reverse transcription digital PCR, to perform as a negative control in assays that detect SARS-CoV-2 RNA. Representative data is presented for reference only in Table 1. Specific performance will vary among different manufacturers’ assays, different procedures, different lot numbers, and different laboratories.

REAGENTS
Item No. 0505-0042 Negative: 81 x 0.4 mL vials
The product is formulated in viral transport media that consists of Tris-buffered saline, with added glycerol, anti-microbial agents, and human plasma proteins.

WARNINGS AND PRECAUTIONS
For In Vitro Diagnostic Use.
CAUTION: The recombinant viruses used to produce the AccuPlex Human RNase P Negative Control are replication defective and heat-inactivated. 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 2. 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.

Handling Precautions
Do not use AccuPlex Human RNase P Negative Control Kit beyond the expiration date. Avoid microbial contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS
Store the AccuPlex Human RNase P Negative Control refrigerated at 2-8°C. The product may be initially stored at -20°C, but once thawed, maintain at 2-8°C. Do not expose to multiple freeze thaw cycles. Vials are not intended to be stored after initial use; discard after initial opening and use. To prevent leakage, store vials upright.

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

PROCEDURE
Materials Provided
AccuPlex Human RNase P Negative Control 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 controls should be added to a test run using the same procedure provided by the manufacturer for unknown specimens. AccuPlex SARS-CoV-2 controls 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 SARS-CoV-2 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 controls do not have assigned values, it is recommended that each laboratory validate the use of each lot of AccuPlex Human RNase P Negative Control kit with each specific assay system prior to its routine use in the laboratory.

INTERPRETATION OF RESULTS
Levels of reactivity for the AccuPlex Human RNase P Negative Control may vary with different manufacturers’ tests and different test kits. This product contains a targeted formulation of 5000 copies/mL, as measured using reverse transcription digital PCR. Each batch is tested using 2019nCoV primers/probes described in the US CDC Assay publication and using testing protocols similar to that described in CDC published instructions for use. The AccuPlex Human RNase P Negative Control gives negative results for SARS-CoV-2 and positive results for RNA P on this assay.

If AccuPlex SARS-CoV-2 controls do not perform as expected, this may be an indication of unsatisfactory test performance. Possible sources of discrepancy are: deterioration of test kit reagents, operator error, faulty performance of equipment, or contamination of reagents.

LIMITATIONS OF THE PROCEDURE
AccuPlex Human RNase P Negative Control Kit MUST NOT BE SUBSTITUTED FOR THE 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 controls are provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedure. Performance characteristics for AccuPlex SARS-CoV-2 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 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 Human RNase Negative Control 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 Human RNase P Negative Control Kit is manufactured from recombinant virus particles in viral transport media. AccuPlex SARS-CoV-2 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.

REFERENCES

Table 1. Representative data for AccuPlex Human RNase P Negative Control Kit. For reference only.

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Product Component</th>
<th>Target</th>
<th>Result</th>
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<tbody>
<tr>
<td>AccuPlex Human RNase P Negative Control</td>
<td>SARS-CoV-2</td>
<td>Negative</td>
<td>LABORATORY DEVELOPED TEST USING US CDC 2019 nCoV REAL TIME PCR PRIMERS AND PROBES</td>
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