GHSA Request for Proposal (RFP)
For COVID-19 laboratory supplies for the diagnosis of SARS-Cov-2
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Introduction:

The African Society for Laboratory Medicine (ASLM) is a Pan-African professional body, working to advocate for the critical role and needs of laboratory medicine and networks throughout Africa. Medical laboratories play a pivotal role in global disease diagnosis, surveillance, outbreak investigation, initiation and monitoring of therapy, as well as research and development.

In collaboration with the US CDC – GHSA team in Ethiopia, ASLM would like to support the COVID-19 prevention and monitoring program. It has been recently communicated that Cepheid has just received the EUA from US FDA for the Xpert® Xpress SARS-CoV-2 test. The Federal Ministry of Health – Ethiopia (FMoH) has nearly 300 GeneXpert machine in the country for TB and EID program. In order to capitalize on this opportunity and use these machines for SARS-Cov-2 detection, ASLM would like to purchase the required materials for the test especially the Xpert Xpress SARS-CoV-2 cartridge and viral transport media.
RFP Objective:

The African Society for Laboratory Medicine (ASLM) is soliciting supplier(s) - manufacturers, Agents, or vendors - to submit a proposal for the timely and efficient delivery of the items in the product list (attached as APPENDIX II to this RFP) to Addis Abeba, Ethiopia.

Scope of Work: For this Requests for Proposal (RFP) project, the requirements for the supplier(s) are to cover a wide range of multifunctional activities to provide all procurement and resources necessary including but not limited to:

- Provide quotes for the requested items and supplies including delivery dates, methods of shipment (air and/or ocean), freight and handling fees;
- Deliver the requested items as per the tender requirements;
- Deliver supplies with the Certificate from the Manufacturer Warranty and the original Country of Origin Certificate;
- All items should be supplied with at least one year of full warranty and expiry date of more than one year.

5 Application comments

Final selection of the supplier(s) will be based on technical, cost and other considerations as deemed necessary by the scope of work. ASLM shall enter into a contract with the selected supplier(s). Duration of contracts shall be up to June 24th 2020. The review shall include checking deliverables in relation to the scope of work and feedback from target country on performance of the contractor(s). Where the supplier(s) fails to meet the contract requirements, ASLM shall communicate formally of its decision.

6. Instructions for submitting proposals

A. The format of the submission, in response to this RFP, must include, but not limited, to the following:
   i. Background on the organization Where the organization is affiliated/has partnerships with other institutions, a description of how this will result in effective implementation of the proposed areas of work should be included.
   ii. How the Respondent proposes to deliver the requested items.
B. Completed proposals shall consist of typewritten pages utilizing 12” font typing. A maximum of 3 pages for the proposal is allowed.
C. The authorized individual representing the Respondent will sign and date the proposal cover sheet. The signatory agent’s printed name, title, name of the organization, address, phone and fax numbers and email address must be provided. Failure to provide a signed copy of the affirmation statement below will be cause for the proposal not to be considered.

I affirm that the information within this proposal, to the best of my knowledge, is true and accurate. Further, I am duly authorized to sign and submit this proposal on behalf of this agency. I fully affirm and understand that failure to meet the requirements of this proposal at the submitted price may result in my organization’s contract being terminated.

D. Include a certificate from FDA and/WHO for the approval or endorsement of the items to be used in a diagnostic laboratory.

Send your completed application by email to tmekonen@aslm.org, and Copy rfpsubmission@aslm.org, atraore@aslm.org, by 31st July, 2020 (11:59 pm EAT).

Point of contact
Direct any written questions or request for information about this RFP to:

Teferi Mekonen, M.Sc., MPH
Program Manager-GHSA & SLIPTA Coordinator
Tel O: +251-11-557-1021
Skype: teferimek
Email: tmekonen@aslm.org
African Society for Laboratory Medicine (ASLM)

7. Evaluation and Award Process
A team of ASLM staff and outside experts will evaluate the applications based on preset standards relevant to the specific RFP objectives. An evaluation matrix with assigned weighted numerical values will be used to rate each applicant. The following represents some, not all, of the criteria that will be used to the assessed feasibility of each Respondent.

1. Does the organization / individual have the right skill set and expertise to accomplish the required assignments?
2. Did the Respondent demonstrate knowledge of ASLM’s project needs and objectives?

ASLM reserves the right (but is not under obligation to do so) to enter into discussions with one or more Respondents in order to obtain clarifications or additional details, to suggest service delivery refinements in the proposal or other aspects of the proposal, or to negotiate the cost proposal. Formal notification to award the
contract and the actual execution of the contract are subject to receipt of funds from the US Centers for Disease Control and Prevention.

Each Respondent submitting a proposal will be notified in writing or via e-mail of ASLM’s decision concerning their proposal. Should your organization be recommended for acceptance, the contract shall be effective on the contract execution date and shall run until June 24th, 2020. All work must be scheduled and completed within the contract period timeframe. Any modifications or extensions must be negotiated in advance, and submitted to ASLM for review and approval. The selected Respondent’s proposal, and any subsequent material submitted in response to requests for additional information, will become the basis of contractual agreements with said Respondent.

8. **Contractual Terms and Conditions**
Responses must be in accordance with the guidelines as specified in this RFP. This RFP does not commit ASLM to accept any proposals submitted, nor is ASLM responsible for any costs incurred in the preparation of responses to this RFP. All materials submitted in response to this RFP or developed during the life of the contract will become the property of ASLM. The detailed itemized budget must be submitted in US dollars and will be evaluated in terms of best value to ASLM.

ASLM reserves the right to delay, amend, reissue or cancel all or part of this RFP at any time without prior notice. ASLM discourages ex parte communication with any Board Member, the public and/or staff member after the deadline for the receipt of proposals. ASLM will be under no obligation to reveal, or discuss with any Respondent on how a proposal was assessed, or to provide any other information relative to the selection process. Respondents whose proposals are not selected will be notified in writing and shall have no claim whatsoever for any kind of compensation.
Appendix I

General conditions

WARRANTY

- The supplier warrants that the items provided by the supplier will be free from defects.
- If not mentioned elsewhere in the PO or the SA, the warranty for any delivered items will not be less than one year from the date of accepting the delivered items. Supplier has to submit a warranty certificate with the invoice and a copy of it to the HAAD’s procurement section.

PAYMENT

- The Purchase Order number must be quoted on all the documents and copy of the Purchase Order and Original Delivery Note should be attached with the invoice.
- The authority will make payment no later than 30 days from the date of receiving invoice.
- All original invoices must be submitted to the Manager of the Finance Department at ASLM.
Appendix II

Specification of laboratory supplies for the diagnosis of SARS-CoV-2

1. Xpert® Xpress SARS-CoV-2 Cartridges

Xpert Xpress SARS-CoV-2 Cartridges with Integrated Reaction Tubes
• Bead 1, Bead 2, and Bead 3 (freeze-dried) 1 of each per cartridge
• Lysis Reagent 1.5 mL per cartridge
• Binding Reagent 1.5 mL per cartridge
• Elution Reagent 3.0 mL per cartridge
A pack of 10 cartridges

2. Viral Transport Medium (VTM)

The VTM should be available in a screw cap plastic tube containing buffered proteins (serum, albumin or gelatin) and antibiotics. The composition of ingredients and the manufacturing of the VTM should follow the WHO and CDC recommendations.

- Hanks balanced salt solution (HBSS)
- Sterile, heat inactivated Fetal Bovine Serum (FBS)
- Gentamicin sulfate
- Amphotericin B
The VTM is provided as a liquid (3 ml) filled in a sterile 13 ml flat bottom tube with a sterile and single-use swab for sample collection. The swab should have flexible shaft and made of cotton and polypropylene.
The VTM shall be stored at +2°C to +8°C.
Shelf life 1 year after the manufacture date.
Package size 50 VTM vials and 50 sterile Swabs
Appendix III

Xpert® Xpress SARS-CoV-2

Instructions for Use
For Use Under an Emergency Use Authorization (EUA) Only

REF XPRSARS-COV2-10

For Use with GeneXpert Dx or GeneXpert Infinity Systems

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1 Proprietary Name
Xpert® Xpress SARS-CoV-2

2 Common or Usual Name
Xpert Xpress SARS-CoV-2

3 Intended Use
The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in either nasopharyngeal swab and/or nasal wash/aspirate specimens collected from individuals suspected of COVID-19 by their healthcare provider.

Testing of nasopharyngeal swab and nasal wash/aspirate specimens using the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Dx and GeneXpert Infinity systems is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high and moderate complexity tests.

Testing of nasopharyngeal swab specimens using the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Xpress System (Tablet and Hub Configurations) is authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal swab specimens and/or nasal wash/aspirate specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the Xpert Xpress SARS-CoV-2 test is intended for use by trained operators who are proficient in performing tests using either GeneXpert Dx, GeneXpert Infinity and/or GeneXpert Xpress systems. The Xpert Xpress SARS-CoV-2 test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

4 Summary and Explanation
An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.¹ Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.²
The Xpert Xpress SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The Xpert Xpress SARS-CoV-2 test contains primers and probes and internal controls used in RT-PCR for the *in vitro* qualitative detection of SARS-CoV-2 RNA in nasopharyngeal swab specimens and/or nasal wash/aspirate specimens.

The term “qualified laboratories” refers to laboratories in which all users, analysts, and any person reporting results from use of this device are proficient in performing real-time RT-PCR assays.

5 **Principle of the Procedure**

The Xpert Xpress SARS-CoV-2 test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from SARS-CoV-2. The Xpert Xpress SARS-CoV-2 test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*.

The Xpert Xpress SARS-CoV-2 test includes reagents for the detection of RNA from SARS-CoV-2 in nasopharyngeal swab specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The nasopharyngeal swab specimen and/or nasal wash/aspirate specimen is collected and placed into a viral transport tube containing 3 mL transport medium. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2 cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

6 **Reagents and Instruments**

**Materials Provided**

The Xpert Xpress SARS-CoV-2 kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

**Xpert Xpress SARS-CoV-2 Cartridges with Integrated Reaction Tubes**

- Bead 1, Bead 2, and Bead 3 (freeze-dried) 1 of each per cartridge
Xpert Xpress SARS-CoV-2

- Lysis Reagent 1.5 mL per cartridge
- Binding Reagent 1.5 mL per cartridge
- Elution Reagent 3.0 mL per cartridge

Disposable Transfer Pipettes 12 per kit
CD 1 per kit
- Assay Definition File (ADF)
- Instructions to import ADF into GeneXpert software
Flyer 1 per kit
- Directions to locate the Product Insert on www.cepheid.com

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the SUPPORT tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling
- Store the Xpert Xpress SARS-CoV-2 cartridges at 2-28°C.
- Do not open a cartridge lid until you are ready to perform testing.
- Do not use a cartridge that is wet or has leaked.

8 Materials Required but Not Provided
- GeneXpert Dx or GeneXpert Infinity systems (catalog number varies by configuration): GeneXpert instrument, computer, barcode scanner, operator manual.
  For GeneXpert Dx System: GeneXpert Dx software version 4.7b or higher
  For GeneXpert Infinity-80 and Infinity-48s systems: Xpertise software version 6.4b or higher

9 Materials Available but Not Provided
SeraCare AccuPlex™ Reference Material Kit, catalog number 0505-0126 (Order Code CEPHEID)

10 Warnings and Precautions

10.1 General
- For in vitro diagnostic use.
- For emergency use only.
- Positive results are indicative of presence of SARS-CoV-2-RNA
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
• Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been evaluated.

⚠️ • Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention³ and the Clinical and Laboratory Standards Institute.⁴

• Follow safety procedures set by your institution for working with chemicals and handling biological specimens.

• Consult your institution’s environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions should check the hazardous waste disposal requirements within their respective countries.

10.2 Specimens
• Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Section 12, Specimen Collection, Transport, and Storage). Specimen stability under shipping conditions other than those recommended has not been evaluated.

10.3 Assay/Reagent
• Do not open the Xpert Xpress SARS-CoV-2 cartridge lid except when adding specimen.
• Do not use a cartridge that has been dropped after removing it from the packaging.
• Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield non-determinate results.
• Do not place the sample ID label on the cartridge lid or on the barcode label on the cartridge.
• Do not use a cartridge with a damaged barcode label.
• Do not use a cartridge that has a damaged reaction tube.

② Each single-use Xpert Xpress SARS-CoV-2 cartridge is used to process one test. Do not reuse processed cartridges.

② Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.
• Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
• Wear clean lab coats and gloves. Change gloves between the handling of each specimen.
• In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution’s standard procedures for a contamination or spill event. For equipment, follow the manufacturer’s recommendations for
decontamination of equipment.

- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution’s environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

11 Chemical Hazards\textsuperscript{5,6}

- **Signal Word:** Warning

- **UN GHS Hazard Statements:**
  - Harmful if swallowed.
  - May be harmful in contact with skin
  - Causes eye irritation.

- **UN GHS Hazard Statements:**

- **Prevention**
  - Wash thoroughly after handling.

- **Response**
  - Call a POISON CENTER or physician if you feel unwell.
  - If skin irritation occurs: Get medical advice/attention.
  - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - If eye irritation persists: Get medical advice/attention.

12 Specimen Collection, Transport, and Storage

Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. See Section 12.1 for swab collection procedure. Nasopharyngeal swab specimens can be stored at room temperature (15–30 °C) for up to 8 hours and refrigerated (2–8 °C) up to seven days until testing is performed on the GeneXpert Instrument Systems.


12.1 Nasopharyngeal Swab Collection Procedure

Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1). Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab into a viral transport tube (3 mL). Break swab at the indicated break line and cap the specimen collection tube tightly.
Figure 1. Nasopharyngeal Swab Collection

12.2 Nasal Wash/Aspirate Collection Procedure

Using a clean 300 µL transfer pipette (supplied), transfer 600 µL of the sample (two draws, using the same transfer pipette) into the 3 mL Xpert Viral Transport Medium tube and then cap the tube.

13 Procedure

13.1 Preparing the cartridge

Important: Start the test within 30 minutes of adding the sample to the cartridge.

1. Remove a cartridge from the package.
2. Check the specimen transport tube is closed.
3. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open cap on the specimen transport tube.
4. Open the cartridge lid.
5. Remove the transfer pipette from the wrapper.
6. Squeeze the top bulb of the transfer pipette completely and then place the pipette tip in the specimen transport tube (see Figure 2).
7. Release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample will be seen in the overflow reservoir bulb of the pipette (see Figure 2). Check that the pipette does not contain bubbles.

8. To transfer the sample to the cartridge, squeeze the top bulb of the transfer pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) in the cartridge shown in Figure 3. Dispose of the used pipette.

9. Close the cartridge lid.

13.2 External Controls
External controls described in Section 9 are available but not provided and may be used in accordance with local, state, and federal accrediting organizations, as applicable.

To run a control using the Xpert Xpress SARS-CoV-2 test, perform the following steps:

1. Mix control by rapidly inverting the external control tube 5 times. Open cap on external control tube.

2. Open the cartridge lid.
3. Using a clean transfer pipette, transfer one draw of the external control sample into the large opening (Sample Chamber) in the cartridge shown in Figure 3.


13.3 Starting the Test

**Note** Before you start the test, make sure that the system contains modules with GeneXpert Dx software version 4.7b or higher or Infinity Xpertise software 6.4b or higher, and that the Xpert Xpress SARS-CoV-2 Assay Definition File is imported into the software.

This section lists the default steps to operate the GeneXpert Instrument System. For detailed instructions, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*, depending on the model that is being used.

**Note** The steps you follow may be different if the system administrator has changed the default workflow of the system.

1. Turn on the GeneXpert Instrument System:
   - **GeneXpert Dx:**
     If using the GeneXpert Dx instrument, first turn on the instrument and then turn on the computer. Log into the Windows operating system. The GeneXpert software may launch automatically or may require double-clicking on the GeneXpert Dx shortcut icon on the Windows® desktop.
     or
   - **GeneXpert Infinity System:**
     If using the GeneXpert Infinity instrument, power up the instrument by turning the power switch clockwise to the **ON** position. On the Windows desktop, double-click the Xpertise Software shortcut icon to launch the software.

2. Log on to the System software. The login screen appears. Type your username and password.

3. In the GeneXpert System window, click **Create Test** (GeneXpert Dx) or **Orders** followed by **Order Test** (Infinity).

4. Scan or type in the Patient ID (optional). If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is shown on the left side of the View Results window and is associated with the test result.

5. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is shown on the left side of the View Results window and is associated with the test result.

6. Scan the barcode on the Xpert Xpress SARS-CoV-2 cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Reagent Lot ID, Cartridge SN, Expiration Date and Selected Assay.

**Note** If the barcode on the Xpert Xpress SARS-CoV-2 cartridge does not scan, then repeat the test with a new cartridge.

7. Click **Start Test** (GeneXpert Dx) or **Submit** (Infinity) if Auto-Submit is not enabled. In
the dialog box that appears, type your password, if required.

**For the GeneXpert Dx Instrument**
A. Locate the module with the blinking green light, open the instrument module door and load the cartridge.
B. Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off and the door will unlock. Remove the cartridge.
C. Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.

**or**

**For the GeneXpert Infinity System**
A. After clicking **Submit**, you will be asked to place the cartridge on the conveyor belt. After placing the cartridge, click **OK** to continue. The cartridge will be automatically loaded, the test will run and the used cartridge will be placed onto the waste shelf for disposal.
B. When all samples are loaded, click on the **End Order Test** icon.

**Note**  Do not turn off or unplug the instruments while a test is in progress. Turning off or unplugging the GeneXpert instrument or computer will stop the test.

14  **Viewing and Printing Results**
For detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual* or the *GeneXpert Infinity System Operator Manual*.

15  **Quality Control**
15.1  **Internal Controls**
Each cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

**Sample Processing Control (SPC)** – Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

**Probe Check Control (PCC)** – Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.

15.2  **External Controls**
External controls may be used in accordance with local, state and federal accrediting organizations as applicable.

16  **Interpretation of Results**
The results are interpreted automatically by the GeneXpert System and are clearly shown in the
View Results window. The Xpert Xpress SARS-CoV-2 test provides test results based on the detection of two gene targets according to the algorithms shown in Table 1.

| Table 1. Xpert Xpress SARS-CoV-2 Possible Results |
|-------------------------------------|-----|-----|-----|
| Result Text                        | N2  | E   | SPC |
| SARS-CoV-2 POSITIVE                | +   | +   | +/- |
| SARS-CoV-2 POSITIVE                | +   | -   | +/- |
| SARS-CoV-2 PRESUMPTIVE POSITIVE    | -   | +   | +/- |
| SARS-CoV-2 NEGATIVE                | -   | -   | +   |
| INVALID                            | -   | -   | -   |

See Table 2 to interpret test result statements for the Xpert Xpress SARS-CoV-2 test.

<table>
<thead>
<tr>
<th>Table 2. Xpert Xpress SARS-CoV-2 Results and Interpretation</th>
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<tbody>
<tr>
<td>Result</td>
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<tr>
<td>SARS-CoV-2 POSITIVE</td>
</tr>
<tr>
<td>SARS-CoV-2 PRESUMPTIVE POSITIVE</td>
</tr>
</tbody>
</table>
## Result Interpretation

<table>
<thead>
<tr>
<th>Result</th>
<th>Interpretation</th>
</tr>
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</table>
| SARS-CoV-2 NEGATIVE | The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected.  
• The SARS-CoV-2 signals for two nucleic acid targets (N2 and E) do not have a Ct within the valid range and endpoint above the minimum setting  
• SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting  
• Probe Check: PASS; all probe check results pass |
| INVALID         | SPC does not meet acceptance criteria. Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) nucleic acids cannot be determined. Repeat test according to the Retest Procedure in IFU (Section 17.2).  
• SPC: FAIL; SPC and SARS-CoV-2 signals do not have a Ct within valid range and endpoint below minimum setting  
• Probe Check – PASS; all probe check results pass |
| ERROR           | Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) nucleic acids cannot be determined. Repeat test according to the Retest Procedure in IFU (Section 17.2).  
• SARS-CoV-2: NO RESULT  
• SPC: NO RESULT  
• Probe Check: FAIL\(^1\); all or one of the probe check results fail  
\(^1\) If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure. |
| NO RESULT       | Presence or absence of the 2019 novel coronavirus (SARS-CoV-2) nucleic acids cannot be determined. Repeat test according to the Retest Procedure in IFU (Section 17.2). A NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.  
• SARS-CoV-2: NO RESULT  
• SPC: NO RESULT  
• Probe Check: NA (not applicable) |
17 Retests

17.1 Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test once according to instructions in Section 17.2, Retest Procedure.

- A **PRESUMPTIVE POSITIVE** indicates the 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present.

- An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.

- An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, or the maximum pressure limits were exceeded.

- A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.

17.2 Retest Procedure

To retest a non-determinate result (**INVALID**, **NO RESULT**, or **ERROR**), use a new cartridge.

Use the leftover sample from the original specimen transport medium tube or new external control tube.


2. Check the specimen transport tube or external control tube is closed.

3. Mix the sample by rapidly invert the specimen transport medium tube or external control tube 5 times. Open the cap on the specimen transport tube or external control tube.

4. Open the cartridge lid.

5. Using a clean transfer pipette (supplied), transfer sample (one draw) to the sample chamber with the large opening in the cartridge.

6. Close the cartridge lid.
Xpert Xpress SARS-CoV-2

18 Limitations

- Performance of the Xpert Xpress SARS-CoV-2 has only been established in nasopharyngeal swab specimens. Specimen types other than nasopharyngeal swab may give inaccurate results.

- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.

- As with any molecular test, mutations within the target regions of Xpert Xpress SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.

- This test cannot rule out diseases caused by other bacterial or viral pathogens.
## Conditions of Authorization for Laboratory and Patient Care Settings

The Cepheid Xpert Xpress SARS-CoV-2 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: [https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm](https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm)

However, to assist clinical laboratories and/or Patient Care Settings using the Xpert Xpress SARS-CoV-2 (referred to in the Letter of Authorization as “Your Product”), the relevant Conditions of Authorization are listed below.

- Authorized laboratories and patient care settings using your product will include with result reports of the Xpert Xpress SARS-CoV-2 test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

- Authorized laboratories using your product will use your product as outlined in the Xpert Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity systems. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Xpert Xpress SARS-CoV-2 test are not permitted.

- Patient Care Settings using your product will use your product as outlined in the Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Xpress System and associated Quick Reference Instructions for Xpert Xpress SARS-CoV-2 and GeneXpert Xpress System (Hub configuration), and Quick Reference Instructions for Xpert Xpress SARS-CoV-2 and GeneXpert Xpress System (Tablet configuration). Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

- Authorized laboratories and patient care settings will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

- Authorized laboratories and patient care settings that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

- Authorized laboratories and patient care settings using the Xpert Xpress SARS-CoV-2 test will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA Reporting@fda.hhs.gov) and Cepheid (+1 888.838.3222 or techsupport@cepheid.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective
equipment when handling this kit, and use your product in accordance with the authorized labeling.

- You, authorized distributors, and authorized laboratories and patient care settings using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

1 The letter of authorization refers to, “United States (U. S.) laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate or high complexity tests” as “authorized laboratories.”
20 Performance Characteristics

20.1 Clinical Evaluation

The performance of the Xpert SARS-CoV-2 test was evaluated using contrived clinical nasopharyngeal (NP) swab specimens in viral transport medium obtained from individuals with signs and symptoms of respiratory illness. The samples were prepared by spiking each individual clinical NP swab sample with AccuPlex SARS-CoV-2 (a quantitated reference material – recombinant Sindbis virus particle containing target sequences from the SARS-CoV-2 genome) at concentrations approximate to 2x LoD, 3x LoD and 5x LoD. The NP swab samples were determined to be negative for SARS-CoV-2 prior to spiking the specimens. Negative NP swab samples were also tested in the study.

Table 3 shows the samples with the target concentrations of the AccuPlex SARS-CoV-2, the number of concordant results and total number tested as well as the percent agreement with the 95% confidence interval (95% CI) where appropriate. The results show 100% agreement with the expected results in the AccuPlex SARS-CoV-2 spiked samples and 100% agreement with the expected results in the negative samples.

<table>
<thead>
<tr>
<th>Target Concentration</th>
<th>Number Concordant/ Number Tested</th>
<th>E Mean Ct</th>
<th>N2 Mean Ct</th>
<th>% Agreement [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>2x LoD</td>
<td>20/20</td>
<td>34.8</td>
<td>38.0</td>
<td>100% [83.9% - 100%]</td>
</tr>
<tr>
<td>3x LoD</td>
<td>5/5</td>
<td>33.7</td>
<td>37.1</td>
<td>100% [NA*]</td>
</tr>
<tr>
<td>5x LoD</td>
<td>5/5</td>
<td>33.7</td>
<td>36.8</td>
<td>100% [NA*]</td>
</tr>
<tr>
<td>Negative</td>
<td>35/35</td>
<td>NA</td>
<td>NA</td>
<td>100% [90.1% - 100%]</td>
</tr>
</tbody>
</table>

* 95% CI not computed for sample concentrations with sample size of 5 or less.

21 Analytical Performance

21.1 Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert Xpress SARS-CoV-2. The LoD of Xpert Xpress SARS-CoV-2 was established using one lot of reagent and limiting dilutions of AccuPlex SARS-CoV-2 prepared in simulated background matrix and nasopharyngeal swab clinical matrix. Verification of the estimated LoD claim was performed on one reagent lot in replicates of 35 prepared in nasopharyngeal swab clinical matrix. The LoD is the lowest concentration (reported as copies/μL) of AccuPlex SARS-Cov-2 recombinant viral sequence that can be reproducibly distinguished from negative samples ≥ 95% of the time with 95% confidence. The claimed LoD for the assay is 250 copies/mL (Table 4).
Table 4. Limit of Detection of the Xpert Xpress SARS-CoV-2

<table>
<thead>
<tr>
<th>Material</th>
<th>Claimed LoD (copies/mL)</th>
<th>Positives/Replicates</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Reference Material</td>
<td>250</td>
<td>35/35</td>
</tr>
</tbody>
</table>

21.2 Analytical Reactivity (Inclusivity)

The inclusivity of Xpert Xpress SARS-CoV-2 was evaluated using in silico analysis of the assay primers and probes in relation to 324 SARS-CoV-2 sequences available in the GISAID gene database for two targets, E and N2.

For the E target, Xpert Xpress SARS-CoV-2 had 100% match to all sequences with the exception of 4 sequences that had a single mismatch. For the N2 target, Xpert Xpress SARS-CoV-2 had 100% match to all sequences with the exception of 2 sequences that had a single mismatch. None of these mismatches found for both targets are predicted to have a negative impact on the performance of the assay, given the location of the mutations in the primer and probe regions respectively for the two variants. These mutations are not predicted to adversely affect the probe and primer binding to the sequences or reduce assay efficiency.

21.3 Analytical Specificity (Exclusivity)

An in silico analysis for possible cross-reactions with all the organisms listed in Table 5 was conducted by mapping primers and probes in the Xpert Xpress SARS-CoV-2 test individually to the sequences downloaded from the GISAID database. E primers and probes are not specific for SARS-CoV-2 and will detect Human and Bat SARS-coronavirus. No potential unintended cross reactivity with other organisms listed in Table 5 is expected based on the in silico analysis.

Table 5. Xpert Xpress SARS-CoV-2 Analytical Specificity Microorganisms

<table>
<thead>
<tr>
<th>Microorganisms from the Same Genetic Family</th>
<th>High Priority Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human coronavirus 229E</td>
<td>Adenovirus (e.g. C1 Ad. 71)</td>
</tr>
<tr>
<td>Human coronavirus OC43</td>
<td>Human Metapneumovirus (hMPV)</td>
</tr>
<tr>
<td>Human coronavirus HKU1</td>
<td>Parainfluenza virus 1-4</td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>Influenza A</td>
</tr>
<tr>
<td>SARS-coronavirus</td>
<td>Influenza B</td>
</tr>
<tr>
<td>MERS-coronavirus</td>
<td>Influenza C</td>
</tr>
<tr>
<td>Bat coronavirus</td>
<td>Enterovirus (e.g. EV68)</td>
</tr>
<tr>
<td></td>
<td>Respiratory syncytial virus</td>
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<tr>
<td></td>
<td>Rhinovirus</td>
</tr>
<tr>
<td></td>
<td>Chlamydia pneumoniae</td>
</tr>
<tr>
<td></td>
<td>Haemophilus influenzae</td>
</tr>
<tr>
<td></td>
<td>Legionella pneumophila</td>
</tr>
<tr>
<td></td>
<td>Mycobacterium tuberculosis</td>
</tr>
<tr>
<td></td>
<td>Streptococcus pneumoniae</td>
</tr>
<tr>
<td></td>
<td>Streptococcus pyogenes</td>
</tr>
<tr>
<td></td>
<td>Bordetella pertussis</td>
</tr>
<tr>
<td>Microorganisms from the Same Genetic Family</td>
<td>High Priority Organisms</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>Mycoplasma pneumoniae</td>
<td>Pneumocystis jirovecii (PJP)</td>
</tr>
<tr>
<td>Parechovirus</td>
<td></td>
</tr>
<tr>
<td>Candida albicans</td>
<td></td>
</tr>
<tr>
<td>Corynebacterium diphtheriae</td>
<td></td>
</tr>
<tr>
<td>Legionella non-pneumophila</td>
<td></td>
</tr>
<tr>
<td>Bacillus anthrasis (Anthrax)</td>
<td></td>
</tr>
<tr>
<td>Moraxella catarrhalis</td>
<td></td>
</tr>
<tr>
<td>Neisseria elongate and meningitidis</td>
<td></td>
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<tr>
<td>Pseudomonas aeruginosa</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td></td>
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<tr>
<td>Staphylococcus salivarius</td>
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<tr>
<td>Leptospira</td>
<td></td>
</tr>
<tr>
<td>Chlamydia psittaci</td>
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<tr>
<td>Coxiella burnetii (Q-Fever)</td>
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<tr>
<td>Staphylococcus aureus</td>
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</tr>
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</table>
22 References


23 Cepheid Headquarters Locations

<table>
<thead>
<tr>
<th>Corporate Headquarters</th>
<th>European Headquarters</th>
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<tbody>
<tr>
<td>Cepheid</td>
<td>Cepheid Europe SAS</td>
</tr>
<tr>
<td>904 Caribbean Drive</td>
<td>Vira Soleh</td>
</tr>
<tr>
<td>Sunnyvale, CA 94089</td>
<td>81470 Maurens-Scopont</td>
</tr>
<tr>
<td>USA</td>
<td>France</td>
</tr>
<tr>
<td>Telephone: +1 408 541 4191</td>
<td>Telephone: +33 563 825 300</td>
</tr>
<tr>
<td>Fax: +1 408 541 4192</td>
<td>Fax: +33 563 825 301</td>
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24 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

<table>
<thead>
<tr>
<th>Region</th>
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<th>Email</th>
</tr>
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<tbody>
<tr>
<td>US</td>
<td>+ 1 888.838.3222</td>
<td><a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a></td>
</tr>
<tr>
<td>France</td>
<td>+ 33 563 825 319</td>
<td><a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a></td>
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# Xpert Xpress SARS-CoV-2

## Table of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
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<tbody>
<tr>
<td><img src="image" alt="REF" /></td>
<td>Catalog number</td>
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<tr>
<td><img src="image" alt="IVD" /></td>
<td><em>In vitro</em> diagnostic medical device</td>
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<tr>
<td><img src="image" alt=" cautiously" /></td>
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<td>Consult instructions for use</td>
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<tr>
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<td>Caution</td>
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<tr>
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<tr>
<td><img src="image" alt="Rx only" /></td>
<td>For prescription use only</td>
</tr>
</tbody>
</table>

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