NHS SUPPLY CHAIN FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS AND SERVICES

Order Form
NHS Supply Chain: Pathology and Point of Care Testing, Associated Equipment, Instruments, Consumables and Accessories and Managed Services (the "Framework Agreement")
(2019/S 212-519575)

Contract number/reference/date: C106527/CRE 4142 /1st October 2022

between the parties referred to below (the "**Contract**")

The Parties:

(1) Cepheid UK Limited, a company registered in England and Wales with number 04422108 whose registered office is at Oakley Court, Kingsmead Business Park, Frederik Place, High Wycombe, HP11 1JU (the "**Supplier**"); and

(2) The Secretary of State for Health and Social Care, acting through the UK Health Security Agency, Nobel House, Smith Square, London, SW1P 3JR, acting as part of the Crown (the "**Authority**");

Whereas:

(A) The Parties hereto have entered into the Contract.

(B) This Schedule is entered into pursuant to the Contract.

It is agreed:

1. Contract

The Contract shall comprise the following terms in the following order of precedence:

1.1 This Order Form and its appendices;
1.2 The terms set out at the front end of this Contract;
1.3 The Call-off Terms and Conditions which are appended to the Framework Agreement as Appendix 3a;
1.4 The Specification; and
1.5 The Framework Agreement (including its Schedules).

Any purchase order issued by the Authority in respect of this Contract does not form part of this Contract.

2. The Goods

2.1. The Authority may order, and the Supplier shall provide, the Cepheid® Xpert Xpress SARS-CoV-2 assay (the **"Tests"**) as specified in Appendix B (the **"Specification"**) for use with the

Cepheid® GeneXpert Systems to be delivered and used within the NHS network over the Term (the **"Goods"**).

2.2. Subject to Clause 7.1 of this Order Form, the Authority shall be entitled to order the Goods, and the Supplier shall provide the Goods.

2.3. The Supplier shall ensure the Goods comply with the Specification set out in Appendix B to this Order Form.

2.4. Only orders placed directly by the Authority are binding under this Contract.

3. Contract Period and Termination

3.1 This Contract shall commence on 1st October 2022 (**"Commencement Date"**) and shall, unless terminated earlier in accordance with its terms, expire on 31st March 2023 (the **"Term"**).

3.2 Without prejudice to any other right of termination set out in this Contract, the Authority may terminate this contract, in whole or in part, for convenience by giving the Supplier not less than twelve (12) weeks' notice in writing.

3.3 Term extension options:

3.3.1 The Authority shall be entitled to extend the Term in accordance with Clause 15.2 of the Call-off Terms and Conditions on one or more occasions by giving the Supplier written notice no less than twelve (12) weeks' notice prior to the date on which this Contract would otherwise have expired; and

3.3.2 The Supplier shall, no later than ten (10) working days after receiving the Extension Requirements provide its proposals to provide the Extension Requirements.

3.3.3 The Parties shall, acting reasonably and in good faith, discuss and agree how the Supplier will meet the Extension Requirements during the Extension Period. These terms shall be rolled into this contract by way of variation.

3.4 Only orders placed directly by the Authority are binding under this contract.

4. Price of Goods

4.1 The maximum value of Goods that may be purchase under this Contract is eight million two hundred and eighty-three thousand and nine hundred and seventy-four pounds (£8,283,974) excluding VAT and inclusive of freight and delivery charges (the **"Contract Price"**). Details of the unit price of the Goods are contained in Appendix A of this Order Form. For the avoidance of doubt, the Authority is not committed to pay the Contract Price.

4.2 As set out in Appendix A to this Order Form, the Cepheid® Xpert Xpress SARS-CoV-2 assay test kit, [redacted]

5 Delivery and Risk:

5.1.1 The Supplier shall deliver agreed quantities of the Goods to locations as directed by the Authority from time to time (the **"Delivery Locations"**). An initial forecast list of Delivery Locations is at Appendix C.

5.1.2 All planned deliveries need to be pre-advised to the Authority at [redacted] (the **"Delivery Contact"**) by the Supplier at least 48 hours prior to shipping. The Delivery Contact in conjunction with the Supplier will then co-ordinate volumes, delivery details for each of the Delivery Locations.

5.1.3 Please provide the following data when notifying the Delivery Contact:

5.1.3.1 Supplier name;

5.1.3.2 Authority's purchase order number;

5.1.3.3 Item reference, Supplier's part code, description and quantity;

5.1.3.4 Item / pallet / carton reference for multi-pallet / carton shipments; and

5.1.4 The Delivery Contact will confirm:

5.1.4.1 Booking reference number;

5.1.4.2 Date and time of delivery slot (where applicable); and

5.1.4.3 Delivery address.

5.1.5 The Supplier shall ensure that all Goods are labelled with the product description, part number, volume, batch number and storage requirements.

5.1.6 Delivery of the Goods shall be considered to have occurred when the Delivery Contact or other authorised representative of the Authority at the Authority's nominated location has signed the delivery note confirming receipt.

5.1.7 Risk will pass to the Authority on the Goods in accordance with clause 2 (Delivery of the Goods and passing of risk and ownership of the Goods) of the Call Off Terms and Conditions.

5.1.8 The Supplier shall carry out deliveries within the ordinary working hours at the delivery location on the date specified in accordance with clause 5.1.4.

6 Return Conditions

The Return Conditions will be as follows:

6.1 The Supplier shall be responsible for collecting the Goods.

6.2 The Supplier shall be responsible for the costs of returning/collecting the Goods.

6.3 In accordance with clause 4.2 of the Call-off Terms and Conditions the Authority will inspect the Goods within 15 Business Days following delivery.

7 Supplementary Conditions and Key Provisions

The following additional terms shall apply:

7.1. Ordering Procedures:

7.1.1. The Authority may, but shall not be obliged to, provide the Supplier with call off orders for test kits and/or Cepheid systems up to, but not exceeding cumulatively the Contract Price.

7.1.2. The Parties agree that the period of 2 WEEKS is adequate notice for the Supplier to deliver up to a maximum of [redacted].

7.1.3. Where the Authority provides the Supplier with a call off order pursuant to clause 7.1.1. above with notice that is not less than the period specified in clause 7.1.2 above then the Supplier shall fulfil such call off order.

7.1.4. Where the Authority provides the Supplier with a call off order pursuant to clause 7.1.1. above with notice that is less than the period specified in clause 7.1.2 above then the Supplier shall use its reasonable endeavours to fulfil such call off order in whole, and where the Supplier is not able to fulfil in whole in part, in the timeframe specified by the Authority.

7.1.5. Where the Authority's call off order made pursuant to clause 7.1.4. has been in the Supplier's possession for a period not less than that set out in clause 7.1.2. above the Supplier shall treat such call off order as if the Authority had submitted it pursuant to clause 7.1.3. accordingly.

7.1.6. Not used.

7.1.7. The Supplier shall, as per the Authority's request, deliver the allocated amount to the relevant designated laboratory or laboratories on the specified Delivery Date(s).

7.1.8. The Supplier shall provide [redacted] with the delivery notes on dispatch of each allocated amount with unique reference numbers.

7.1.9. The Supplier shall provide [redacted] with a consolidated summary of the delivered allocated amounts on a monthly basis to allow verification of invoices and proof of delivery at each Delivery Location.

7.1.10. The Supplier shall not accept any requests under this Contract, made directly to the Supplier, by the Delivery Locations, including but not limited to any variance to the weekly delivery.

7.1.11. The Supplier shall provide fortnightly delivery information, as defined by the Authority, of all Delivery Sites via spreadsheet and, in line with the Authority's requirement of all Suppliers, shall make weekly reporting available to the Authority via the Cactus Portal.

7.1.12. In the event of an error of the system that results in the loss of Goods that is not a result of Authority operator negligence the Supplier shall replace lost materials free of charge.

7.1.13. The Parties reserve the right to modify the above process, by written agreement of both Parties, during the Term of this Contract.

7.2. **Performance Standards**

7.2.1. The Supplier agrees to conform to the following key performance indicators (**"KPIs"**) during the Term of this Contract:

7.2.1.1. Deliveries on the agreed quantities on the due day (for the avoidance of doubt: (a) deliveries which arrive on time but are not unloaded due to the driver's decision; (b) deliveries which do not arrive; and (c) deliveries which arrive at the wrong delivery location, shall also be considered late).

7.2.1.2. Quantity of delivery correct against the relevant Order as per Orders placed in accordance with Clauses 5 and 7 for this Order Form.

7.2.1.3. Quality of delivery in accordance with this Contract, including delivery presentation (the delivery must be presented in such a way that it can be unloaded safely and in a ready for use condition taking into consideration this Contract's requirements) and condition of the Goods (the Goods must be in a condition that is new and ready to use).

7.2.1.4. Timely and accurate administration (including booking/amending delivery times and Orders and invoices, delivery advice notes and labels being in accordance with the requirements of this Contract)

7.2.2. The Supplier shall ensure that the Goods shall perform to the standards detailed within Appendix B of this Order Form.

7.3. Invoicing Terms

7.3.1. Payment terms are net 30 days from receipt of a valid invoice.

7.3.2. Within 10 business days of receipt of the Supplier's countersigned copy of the Contract, the Authority will send a unique purchase order (the **"PO"**) number. The Supplier must be in receipt of a valid PO number before submitting an invoice.

7.3.3. The Supplier shall provide an invoice to the Authority for all Goods received and accepted by the Authority in the relevant period.

7.3.4. All invoices must be sent for approval to the Authority's designated finance mailbox e-mail: [redacted] and their agreed representative before being submitted for payment.

7.3.5. All invoices must be sent quoting a valid purchase order number. The Supplier shall provide a current statement of accounts on a monthly basis; this is a standard commercial process and should show all invoices raised and amounts outstanding.

7.3.6. The Supplier shall provide compliant invoices that includes, as a minimum, a valid PO number, PO line item number (if applicable), PO line description, and the details (name and telephone number) of the Authority's authorised representative. Non – compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment.

7.3.7. The Supplier shall provide to the Authority a signed delivery note evidencing receipt of the Goods at the Authority's nominated Delivery Locations to [redacted]

7.3.8. Supplier queries regarding payment shall be sent to the Authority's Accounts Payable section, by email to [redacted]

7.3.9. The Authority shall have the right to audit Supplier stock at any time on not less than 5 business days' notice. The Parties shall be responsible their own expenses or costs that occur as part of any of these audits.

8 Contract Managers

The Suppliers Contract Manager is:

Name: [redacted]

[redacted]

The Authority's Contract Manager is:

[redacted]

[redacted]

For the purposes of clause 27.1 of the Call-off Terms and Conditions, notices shall be sent to:

For the Supplier:

Oakley Court
Kingsmead Business Park
Frederik Place
High Wycombe
HP11 1JU

For the Authority:

[redacted]
Nobel House, Smith Square,
London,
SW1P 3JR

9 Management Information and meetings

9.1 The Authority's Contract Manager (or their delegate) and Supplier's Contract Manager shall meet weekly (or such other frequency as reasonably requested by the Authority) to discuss the Supplier's performance and other matters connected to the delivery of this Contract.

9.2 The Supplier shall provide any management information required as outlined at clause 9 below in accordance with the Framework (including, for the avoidance of doubt, monthly statements), or such other information as reasonably requested by the Authority, as requested by the Authority from time to time, within seven (7) Business Days of the date of such request.

9.3 The Supplier will provide details on the deliveries weekly, as part of contract management meetings, which may take place monthly and the Supplier will provide a monthly report. Such meetings will be attended by the Authority's Contract Manager (or their delegate) and Supplier's Contract Manager

9.4 The Authority can request the following information from the Supplier at any time and request contract management meetings to be set up to monitor the following:

9.4.1 The KPIs, including as specified in Clause 7.2 of this Order Form;

9.4.2 Stock Level held by Supplier;

9.4.3 Stock Level held by the Supplier at the Authority's request;

9.4.4 Issues; and

9.4.5 Invoicing.

9.4.6 Any Other Business

9.5 The Supplier shall provide a management report on a monthly basis providing delivery volumes, broken down by Site.

10 Quality Assurance Standards for the Goods

10.1 The Quality Assurance standards set out below shall apply to the Goods:

10.1.1 The Framework Quality Standards apply.

10.1.2 In addition, as the Goods are CE marked clause 10.2 of the Call-off Terms and Conditions shall apply.

11 Requirements for Use by Dates

The Supplier shall supply the Goods with a shelf life of no less than 10 months from the delivery date of the Goods. Where the Supplier cannot meet the 10 month shelf life, the Supplier shall inform the Authority of the shelf life of the Goods proposed to be delivered for the Authority's approval.

12 Data Protection Protocol

The Supplier shall Process Personal Data under or in connection with this Contract in accordance with the Data Protection Protocol as supplied by the Authority to the Supplier as part of this Order Form (if any).

This Contract has been entered into on the day and date given below:

Signed by
for and on behalf of the Supplier

[redacted]

Date Signed: 25/10/2022

Signed by
for and on behalf of the Authority

[redacted]

Date Signed: 26/10/2022

NHS SUPPLY CHAIN FRAMEWORK AGREEMENT FOR THE SUPPLY OF GOODS AND SERVICES

Appendix A
Goods/Contract Price

Report Classification	Mat. Number	Description	Unit Price
[redacted]	XPRSARS-COV2-10	Cepheid® Xpert Xpress SARS-CoV-2 assay	[redacted]

Appendix B
Specifications for the Goods

GeneXpert
Powered By CEPHEID INNOVATION

Xpert® Xpress SARS-CoV-2

Instructions for Use

REF XPRSARS-COV2-10

For Use with GeneXpert Dx or GeneXpert Infinity Systems

Cepheid. *In Vitro* Diagnostic Medical Device CE IVD 302-3787, Rev. B October 2020

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Xpert® Xpress SARS-CoV-2

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 real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimen collected from individuals who are suspected of COVID-19 infection.

Results are for the identification of SARS-CoV-2 RNA. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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.

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.

The Xpert Xpress SARS-CoV-2 test is intended to be performed by trained users in both laboratory and near patient testing settings.

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 was later renamed SARS-CoV-2 by the International Committee for Taxonomy of Viruses (ICTV).[2] The WHO declared the outbreak a global health emergency on January 30, 2020. SARS-CoV-2 has been responsible for over a million reported cases of Coronavirus infectious disease 2019 (COVID-19) worldwide. The morbidity and mortality of COVID-19 varies by patient age and risk factors, with the elderly and those with co-morbidities such as hypertension, diabetes, and respiratory disease at most risk.

The Xpert Xpress SARS-CoV-2 test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of 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 (NP) swab, nasal swab, or nasal wash/aspirate specimens.

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 NP swab, nasal swab, or nasal wash/aspirate specimen. 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 NP swab, nasal swab, or nasal wash/aspirate specimen is collected and placed into a transport tube containing 3 mL of viral transport medium or 3 mL of saline. 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

6.1 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	**10**
• 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
Disposable Transfer Pipettes	**10-12 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.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 postmortem 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

- Nylon flocked swab (Copan P/N 502CS01, 503CS01) or equivalent
- Viral transport medium, 3 mL (Copan P/N 330C) or equivalent
- 0.85% (w/v) saline, 3 mL
- Sample Collection Kit for Viruses (Cepheid P/N SWAB/B-100, SWAB/M-100, SWAB/F-100) or equivalent
- 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.
- Positive results are indicative of presence of SARS-CoV-2 RNA.
- Report all positive results to the appropriate health authorities as required.
- 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 Prevention[3] 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.
- Each single-use Xpert Xpress SARS-CoV-2 cartridge is used to process one test. Do not reuse processed cartridges.
- 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[5,6]

- Signal Word: WARNING
- **UN GHS Hazard Statements**
  - Harmful if swallowed.
  - May be harmful in contact with skin.
  - Causes eye irritation.
- **UN GHS Precautionary Statements**
  - **Prevention**
    - Wash hands thoroughly after handling.
  - **Response**
    - Call a POISON CENTER or doctor/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 nasopharyngeal swab collection procedure, Section 12.2 for nasal swab collection procedure, and Section 12.3 for nasal wash/aspirate collection procedure.

Nasopharyngeal swab, nasal swab and nasal wash/aspirate specimens can be stored in viral transport medium or saline, at room temperature (15-30 °C) for up to 8 hours and refrigerated (2-8 °C) up to 7 days until testing is performed on the GeneXpert Instrument Systems.

Refer to the WHO Laboratory Biosafety Guidance Related to the Coronavirus Disease 2019 (COVID-19).

https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19)

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 the tube containing 3mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.

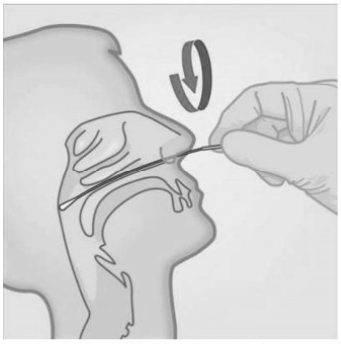

Figure 1. Nasopharyngeal Swab Collection

12.2 Nasal Swab Collection Procedure

1. Insert a nasal swab 1 to 1.5 cm into a nostril. Rotate the swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril (see Figure 2).

Figure 2. Nasal Swab Collection for First Nostril

2. Repeat on the other nostril with the same swab, using external pressure on the outside of the other nostril (see Figure 3). To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the nostril.

Figure 3. Nasal Swab Collection for Second Nostril

3. Remove and place the swab into the tube containing 3 mL of viral transport medium or 3 mL of saline. Break swab at the indicated break line and cap the specimen collection tube tightly.

12.3 Nasal Wash/Aspirate Collection Procedure

1. Nasal wash/aspirate specimens can be collected following the user institution standard procedure. Also, refer to the WHO guidelines for the collection of human nasal wash/aspirate specimens. https://www.who.int/influenza/human_animal_interface/virology_laboratories_and_vaccines/guidelines_collection_h5n1_humans/en/
2. Using a transfer pipette, transfer 600 µL of the undiluted nasal wash/aspirate specimen into the tube containing 3 mL of viral transport medium or 3 mL of saline 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 4).

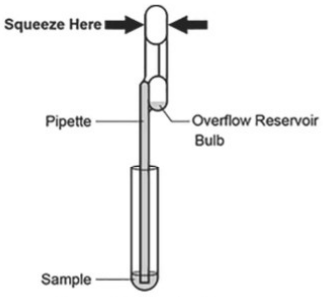

Figure 4. Transfer Pipette

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 4). 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 (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 5. Dispose of the used pipette.

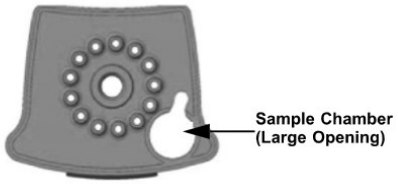

Figure 5. Xpert Xpress SARS-CoV-2 Cartridge (Top View)

Note Take care to dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.

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 (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Figure 5.
4. Close cartridge lid.

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 user name 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

CONTROL

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 should 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 PRESUMPTIVE POS	-	+	+/-
SARS-CoV-2 NEGATIVE	-	-	+
INVALID	-	-	-

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

Table 2. Xpert Xpress SARS-CoV-2 Results and Interpretation

Result	Interpretation
SARS-CoV-2 POSITIVE	The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected. • The SARS-CoV-2 signal for the N2 nucleic acid target or signals for both nucleic acid targets (N2 and E) have a Ct within the valid range and endpoint above the minimum setting • SPC: NA; SPC is ignored because coronavirus target amplification occurred • Probe Check: PASS; all probe check results pass
SARS-CoV-2 PRESUMPTIVE POS	The 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present. Sample should be retested according to the Retest Procedure in Section 17.2. For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. • The SARS-CoV-2 signal for only the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting • SPC: NA; SPC is ignored because a target amplification has occurred. • Probe Check: PASS; all probe check results pass
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 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

Table 2. Xpert Xpress SARS-CoV-2 Results and Interpretation (Continued)

Result	Interpretation
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 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, no sample added, 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 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)

The Xpert Xpress SARS-CoV-2 test includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens if the signal from the target nucleic acid reaches a predetermined threshold before the full 45 PCR cycles have been completed. When SARS-CoV-2 titers are high enough to initiate the EAT function, the SPC amplification curve may not be seen and its results may not be reported.

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 POS** result indicates the 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present. Only one of the SARS-CoV-2 nucleic acid target was detected (E gene) while the other SARS-CoV-2 nucleic acid target (N2 gene) was not detected.
- 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, no sample added, 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**) or a **PRESUMPTIVE POS** result, use a new cartridge.

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

1. Put on a clean pair of gloves. Obtain a new Xpert Xpress SARS-CoV-2 cartridge and a new transfer pipette.
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.

18 Limitations

- 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.
- 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.

19 Performance Characteristics

19.1 Clinical Evaluation

The performance of the Xpert Xpress SARS-CoV-2 test was evaluated using archived clinical nasopharyngeal (NP) swab specimens in viral transport medium. A total of 45 SARS-CoV-2 positive and 45 SARS-CoV-2 negative NP swab specimens were tested with Xpert Xpress SARS-CoV-2 in a randomized and blinded fashion.

All the 45 SARS-CoV-2 positive specimens and 30 of the 45 SARS-CoV-2 negative specimens were collected during COVID-19 pandemic in the US and had previously been characterized as positive or negative for SARS-CoV-2 by an EUA RT-PCR test. Fifteen of the 45 SARS-CoV-2 negative NP swab specimens were collected before December 2019 and are expected to be negative for SARS-CoV-2.

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Xpress SARS-CoV-2 test relative to the expected results. Results of these 90 archived clinical NP swab specimens are shown in Table 3. The PPA was 97.8% (95% CI: 88.4% - 99.6%) and the NPA was 95.6% (95% CI: 85.2% - 98.8%).

Table 3. Xpert Xpress SARS-CoV-2 Performance Results

		Expected Results		
		Positive	**Negative**	**Total**
Xpert Xpress SARS-CoV-2	**Positive**	44[a]	2[b]	46
	Negative	1	43	44
	Total	45	45	90
PPA		97.8% (95% CI: 88.4% - 99.6%)		
NPA		95.6% (95% CI: 85.2% - 98.8%)		

a. One specimen was reported as "SARS-CoV-2 Presumptive Pos" in initial testing and yielded a "SARS-CoV-2 Positive" test result upon retesting.
b. The two false positive specimens were collected during the COVID-19 pandemic.

20 Analytical Performance

20.1 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 live SARS-CoV-2 virus (USA_WA1/2020) prepared in viral transport medium and NP swab clinical matrix. The concentration level with observed hit rates greater than or equal to 95% in the LoD determination study were 0.0050 and 0.0200 PFU/mL for the N2 target and E target, respectively (Table 4). Verification of the estimated LoD claim was performed on one reagent lot in replicates of 20 prepared in pooled NP swab clinical matrix. The LoD is the lowest concentration (reported as PFU/mL) of live SARS-CoV-2 virus samples that can be reproducibly distinguished from negative samples ≥ 95% of the time with 95% confidence. The claimed LoD is 0.0200 PFU/mL (Table 4).

Table 4. LoD Determination using USA-WA1/2020 Strain

Strain	Concentration (PFU/mL)	Total Valid Results	Hit Rate (%) N2 Target	Hit Rate (%) E Target	Mean Ct N2 Target	Mean Ct E Target
SARS-CoV-2 virus (USA_WA1/2020)	0.0200	20	100	95.0	38.3	36.4
	0.0050	22	95.5	68.2	40.5	39.1
	0.0025	22	90.9	36.4	41.5	39.6
	0.0010	22	50.0	18.2	42.0	42.0
	0.0005	22	45.5	18.2	41.7	41.5
	0.0003	22	18.2	4.5	42.1	44.9
	0.0001	22	9.1	0	42.9	N/A
	0	0	0	0	N/A	N/A

20.2 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 36,863 SARS-CoV-2 sequences available in the GISAID gene database for two targets, E and N2.

For the E target, 142 matching sequences were excluded due to ambiguity codes, which reduced the total to 36,721 sequences. Xpert Xpress SARS-CoV-2 had 99.4% match to the sequences with the exception of 187 sequences that had a single mismatch and 18 sequences with additional mismatches. Of the 18 sequences with additional mismatches, one sequence contained 2 mismatches in the forward primer region, three sequences contained a 5-nucleotide gap, 2 sequences contained multiple mismatches at the 3' end of the amplicon, and twelve sequences contained a 'AA' dinucleotide but this lies between the oligonucleotides used in the assay. None of these mismatches are expected to affect the performance of the assay.

For the N2 target, 132 matching sequences were excluded due to ambiguity codes, which reduced the total to 36,731 sequences. Xpert Xpress SARS-CoV-2 had 98.9% match to the sequences with the exception of 262 sequences that had a single mismatch and one sequence contained 3 mismatches. None of these mismatches are predicted to have a negative impact on the performance of the assay.

20.3 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

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

20.4 Interfering Substances

Potentially interfering substances studies have been conducted for previous Xpert Flu/RSV tests developed for the GeneXpert system, including Xpert Xpress Flu/RSV and Xpert Flu/RSV XC tests and assay interference was not observed in these studies. Further testing evaluating potentially interfering substances was not conducted with the Xpert Xpress SARS-CoV-2 test. The Xpert Xpress SARS-CoV-2 test uses conventional well-established nucleic acid extraction methods that are utilized with the Xpert Xpress Flu/RSV and Xpert Flu/RSV XC tests. In addition, the Xpert Flu/RSV tests are validated for use with the same specimen types, nasopharyngeal swabs and/or nasal wash/aspirates specimens, as the Xpert Xpress SARS-CoV-2 test. Therefore, assay interference from these substances is not expected for the Xpert Xpress SARS-CoV-2 test.

20.5 Carry-over Contamination Study

Carry-over studies have been conducted for previous Xpert tests developed for the GeneXpert system, including Xpert Xpress Flu/RSV, and no contamination due to carry-over was observed. Further testing for carry-over contamination was not conducted for Xpert Xpress SARS-CoV-2. To minimize test-to-test contamination, specimen and fluids including amplicons are contained within the single-use, disposable cartridge. The self-contained cartridge design prevents the GeneXpert instrument coming into contact with any fluids within the cartridge. Precise fluidic handling within the enclosed cartridge is driven by the syringe and valve, commanded by the assay definition file (ADF) and automated by the GeneXpert instrument. No manual pipetting step is required other than the addition of the specimen to the cartridge by the user prior to the cartridge being placed on the instrument. Once the specimen is added to the cartridge the lid is closed. Thus the instrument and cartridge design are a closed system which minimizes the potential for carry-over.

21 Reproducibility

The reproducibility of the Xpert Xpress SARS-CoV-2 test was established at three sites using a 5-member panel including one negative sample, two low positive (~1.5x LoD) and two moderate positive (~3x LoD) samples. The negative sample consisted of simulated matrix without target microorganism or target RNA. The positive samples were contrived samples in a simulated matrix using either AccuPlex™ SARS-CoV-2 reference material (targeting the N2 and E genes) or inactivated SARS-CoV Urbani strain (targeting the E gene).

Testing was conducted over six (6) days, using three (3) lots of Xpert Xpress SARS-CoV-2 cartridges at three (3) participating sites each with two (2) operators to yield a total of 144 observations per panel member (3 Sites x 2 Operators x 3 Lots x 2 Days/ Lot x 2 Runs x 2 Reps = 144 observations/panel member). The results from the study are summarized in Table 6.

Table 6. Summary of Reproducibility Results - % Agreement by Study Site/Operator

Sample	Site 1			Site 2			Site 3			% Total Agreement[a] by Sample
	Op1	Op2	Site	Op1	Op2	Site	Op1	Op2	Site	
Negative	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
SARS-CoV-2 Low Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	95.8% (23/24)	97.9% (47/48)	95.8% (23/24)	100% (24/24)	97.9% (47/48)	98.6% (142/144)
SARS-CoV-2 Mod Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
SARS-CoV Low Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)
SARS-CoV Mod Pos	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (24/24)	100% (24/24)	100% (48/48)	100% (144/144)

a. Agreement was calculated as the percentage of observed results that were in agreement with the expected results.

22 References

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed February 9, 2020.
2. bioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed March 3, 2020.
3. Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical laboratories* (refer to latest edition). http://www.cdc.gov/biosafety/publications/
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline.* Document M29 (refer to latest edition).
5. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC) No 1907/2007).
6. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

23 Cepheid Headquarters Locations

Corporate Headquarters	European Headquarters
Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France
Telephone: +1 408 541 4191	Telephone: +33 563 825 300
Fax: +1 408 541 4192	Fax: +33 563 825 301
www.cepheid.com	www.cepheidinternational.com

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

Region	Telephone	Email
US	[redacted]	
France		

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.

25 Table of Symbols

Symbol	Meaning
REF	Catalog number
IVD	*In vitro* diagnostic medical device
2	Do not re-use
LOT	Batch code
CE	CE marking - European Conformity
EC REP	Authorized representative in the European Community
	Consult instructions for use
	Caution
	Manufacturer
	Country of manufacture
	Contains sufficient for <n> tests
CONTROL	Control
	Expiration date
	Temperature limitation
	Biological risks

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

EC REP
Cepheid Europe SAS
Vira Solelh
81470 Maurens-Scopont

[redacted]

CE IVD

Appendix C
Initial Delivery Locations

DHSC site distribution

Account name	Hospital Site Code	Trust
Arrowe Park Hospital	RBL14	Wirral University Teaching Hospital NHS FT
Birmingham City Hospital	RXK02	Sandwell and West Birmingham NHS Trust
Birmingham Heartlands Hospital	RRK97	University Hospitals Birmingham NHS Foundation Trust
Calderdale Royal Hospital	RWY02	Calderdale & Huddersfield NHS FT
Cumberland Infirmary	RNN62	North Cumbria University Hospitals NHS Trust
Frimley Park Hospital	RDU01	Frimley Health NHS Foundation Trust
Good Hope Hospital	RRK98	University Hospitals Birmingham NHS Foundation Trust
Tunbridge Wells Hospital	RWFTW	Maidstone and Tunbridge Wells NHA Trust
Maidstone Hospital	RN7C2	Maidstone and Tunbridge Wells NHA Trust
James Paget Hospital	RGP75	James Paget University Hospital NHS Foundation Trust
Leeds General Infirmary	RR801	Leeds Teaching Hospitals NHS Trust
St James's Leeds	RR813	Leeds Teaching Hospitals NHS Trust
Luton & Dunstable Hospital	RC971	Bedfordshire Hospital NHS Foundation Trust
Norfolk & Norwich Uni Hosp & QE Kings Lynn	RM102	Norfolk and Norwich University Hospitals NHS Foundation Trust
Northampton General Hospital	RNS01	Northampton General Hospital NHS Trust
Queen Elizabeth Hospital (Birmingham)	RRK02	University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital (Lewisham)	RJ231	Lewisham and Greenwich NHS Trust
Royal Berkshire Hospital	RHW01	Royal Berkshire NHS Foundation Trust
Royal Bolton Hospital	RMC01	Bolton NHS FT
Royal Stoke Uni Hospital	RJE01	University Hospitals of North Midlands NHS Trust
Royal Surrey County Hospital	RA201	Royal Surrey NHS Foundation Trust
Sandwell General Hospital	RXK01	Sandwell and West Birmingham NHS Trust
SWLP St Georges (ST Georges/Kingston/Croydon/Epsom)	RJ701	St George's University Hospitals NHS Foundation Trust
Croydon	RJ611	South West London Pathology (SWLP)
Kingston	RAX01	SWLP
Epsom & St Helier	RVR50	SWLP
St Peters Hospital	RTK01	Ashford and St Peter's Hospitals NHS Foundation Trust
St Thomas Hospital	RJ100	Guys and St Thomas' NHS Foundation Trust
Guys Hospital	RJ100	Guys and St Thomas' NHS Foundation Trust
Walsall Manor Hospital	RBK02	Sandwell and West Birmingham NHS Trust
Wexham Park Hospital	RDU50	Frimley Health NHS Foundation Trust
William Harvey Hospital/QE Margate/Kent & Canterbury	RVV01	East Kent Hospitals NHS Foundation Trust
Poole Hospital	RD300	Poole Hospital NHS FT

Royal Liverpool University Hospital	REMRQ	Liverpool University Hospital NHS FT
Dorset Hospital	RBD01	Dorset County Hospital NHS FT
Charing Cross hospital	RYJ02	Imperial college NHS Trust
Royal Preston Hospital	RXN02	Lancashire Teaching Hospitals
West Suffolk Hospital	RGR50	West Suffolk NHS Foundation Trust
Royal Devon & Exeter	RH801	Royal Devon & Exeter NHS FT
North Devon District Hospital	RBZ12	Northern Devon Healthcare NHS Trust
James Cook University Hospital	RTRAT	South Tees Hospitals NHS Foundation Trust
Scotland		Sites to be advised
Wales		Sites to be advised
Northern Ireland		Sites to be advised