Cepheid GeneXpert® System and Xpert® Xpress SARS-CoV-2* (CE-IVD and EUA)

	QUESTIONS & ANSWERS	LINKS / REFERENCES
SPECIMEN MANAGEMENT		
1	**What is the specimen of choice?**	
	Nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimen (CE-IVD)	Package Insert
	Nasopharyngeal swab, nasal swab, mid-turbinate swab, oropharyngeal swab or nasal wash/aspirate specimen (EUA)	
2	**List other specimens which can be used:**	
	Other specimens have not been verified and must be discussed with the Cepheid Medical Scientific Affairs team	MedicalScientific.Affairs @cepheid.com
3	**What is the preferred sample collection device?**	
	3 mL Viral transport medium (Copan P/N 330C) or equivalent 3ml 0.85% (w/v) saline Nylon flocked swab (Copan P/N 502CS01, 503CS01) or equivalent Sample Collection Kit for Viruses (Cepheid P/N SWAB/B-100, SWAB/F-100)	Package Insert
4	**List other recommended specimen collection device(s), if any:**	
	Other specimen collection devices have not been verified and must be discussed with the Cepheid Medical Scientific Affairs team	MedicalScientific.Affairs @cepheid.com
5	**What are the appropriate storage conditions for the collected samples?** (Please indicate the recommended temperature range for specimen storage and transportation.)	
	Viral Transport Medium or saline containing: Nasopharyngeal swab, nasal swab or nasal wash/aspirate specimens can be stored as follows: Up to 8 hours (15-30 Degrees Celsius)	Package Insert

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SPECIMEN MANAGEMENT		
6	**How long can the specimen be allowed to stand before processing?**	
	Start the test within 30 minutes after adding the sample to the cartridge	Package Insert
7	**Are there any key points which require additional attention during the specimen collection process to obtain high quality specimens for your test? Please indicate below, if any.**	
	Refer to Cepheid Specimen collection guidance	Package Insert
8	**Can saline solution be used if no viral transport media is available?** (If yes, indicate how much time is recommended for the sample to stay in the saline solution.)	
	Yes, saline solution can be used. Once the sample has been added to the saline solution, cartridge preparation steps can be performed straight away.	Package Insert
REAGENT AND EQUIPMENT MANAGEMENT		
9	**What are the storage requirements of the device/kit?** (Please indicate any temperature, humidity, and any other applicable storage requirements.)	
	2–28°C	Package Insert
10	**How stable is the device/kit after opening?** (Please indicate if the shelf life upon opening varies with the originally assigned shelf life.)	
	Open the cartridge lid only when adding the sample, close the lid and proceed with processing the cartridge.	Package Insert
11	**What are the power and installation requirements of the equipment?** (Please indicate electrical [input voltage, UPS, etc.], as well as installation, requirements, if any.)	
	Rated Voltage:100–240 V~, 50-60 Hz Rated Current GX-I:1.5A @ 100V~, 0.75 A @ 200V~ Rated Current GX-II:1.5A @ 100V~, 0.75 A @ 200V~ Rated Current GX-IV:1.9A @ 100V~, 0.95 A @ 200V~	Cepheid systems brochure

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REAGENT AND EQUIPMENT MANAGEMENT		
12	**What is the throughput of the test system per 8hr-work schedule, keeping in mind that we need to ramp up testing in all the community settings?** (Please indicate the minimum and maximum number of tests [samples and controls] that can be performed per run as well as the expected time per run.)	
	The test is complete in approximately 45 minutes. Early Assay Termination allows the reporting of positive results* in as soon as 30 minutes. System throughput depends on the number of modules present on the system.	https://www.cepheid.com/coronavirus
13	**What is the turn-around time for the test?**	
	The test can provide rapid detection of the current pandemic Coronavirus SARS-CoV-2 in as soon as 30 minutes for positive results*.	https://www.cepheid.com/coronavirus
14	**Is calibration required?** (If yes, please indicate how often, as well as where and how calibration support can be obtained.)	
	Cepheid performs all of the necessary module calibrations before the system is shipped.	
15	**How often is maintenance/servicing required?** (Please indicate any maintenance/servicing support if available.)	
	The maintenance of the instrument can and must be done by users where Cepheid local teams are not available. Maintenance tasks are divided into daily, weekly, monthly, as necessary, quarterly and yearly maintenance tasks. Maintenance procedures may be performed more frequently according to the	
16	**Is the device/equipment/kit a standalone or does it require complimentary lab equipment?** (Mention any required accessories.)	
	Recommended Accessories - UPS and Surge protector Optional Accessories - Batteries/Power generator or Printer	
17	**Can the equipment/device/platform accommodate other programs/modules which are not specifically designed by your company?** (Please describe the compatibility of your device/equipment with other programs, as well as samples [e.g. genetic material] originating from different protocols.)	
	All components used with the GeneXpert system are specific to the GeneXpert system and are not compatible with other manufacturers components.	

	QUESTIONS & ANSWERS	LINKS / REFERENCES
REAGENT AND EQUIPMENT MANAGEMENT		
18	**Can kits from another company be used on your equipment?**	
	No	
19	**Is technical/troubleshooting support available for the device/equipment?** (If available, please specify the type of support [online, telephone, in-person, etc.].)	
	In person and over the telephone via the local Authorized Service Provider or Distributor in your country.	Package Insert
PERFORMANCE CHARACTERISTICS		
20	**What are the performance characteristics of the test for COVID-19?** (Please provide numerical values.)	
	Clinical evaluation: The overall performance of Xpert Xpress SARS-CoV-2 for 30 samples combined shows a positive percent agreement (PPA) of 100% (95% CI: 88.7% - 100%) and a negative percent agreement (NPA) of 100% (95% CI:88.7% - 100%).	Package Insert
21	**What is the limit of detection of the test?**	
	Analytical Sensitivity: The claimed LoD for the assay using Live SARS-CoV-2	Package Insert
BIOSAFETY		
22	**Is a biosafety cabinet required for the test?**	
	Please refer to WHO Laboratory biosafety guidance related to coronavirus disease (COVID-19)	https://www.who.int/publications/i/item/laboratory-bi
23	**What biosafety level is required to perform the test or operate the device ( )?**	
24	**How should kit components/devices be disposed?** (Please indicate if there is any kit component that contains chemicals for which additional attention is required.)	
	Xpert® Xpress SARS-CoV-2 contains Guanidium Thiocyanate. Safety Data Sheet can be accessed on the Cepheid website: https://www.cepheid.com/coronavirus	1.https://www.cepheid.com/coronavirus 2.www.who.int/water_sanitation_health/medicalwast

	QUESTIONS & ANSWERS	LINKS / REFERENCES
TEST SYSTEM / PROCEDURES / CONTROLS		
25	**What is the underlying technology?** (Please specify [PCR, IgG/IgM capture, etc.].) PCR	Package Insert
26	**Are there any steps in the procedure which require particular reaction conditions?** (Please specify any temperature and humidity-sensitive incubations.) N/A	
27	**What are the indicators of a successful test?** A valid test result	Package Insert
28	**What are the indicators of a failed run?** 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	Package Insert
29	**What factors could potentially affect the test?** (Describe the stability of the test with factors including but not limited to: viral transport media, anticoagulants [for serological assays], heat/chemical inactivation, etc.) Improper specimen collection The performance of this assay with other specimen types or samples has not been evaluated. Inadequate numbers of organisms are present in the specimen. Improper transport or storage of collected specimen	Training PPT 302-3815
30	**Does the system incorporate controls? If so, how many?** (Please describe.) On-board internal controls for each sample are: ? Probe Check Control (PCC) ? Sample Processing Control (SPC) Commercially Available External Controls for Xpert® Xpress SARS-CoV-2 can be purchased from Saracara. Use the Order Code GERUEIP	Xpert Xpress SARS-CoV-2 Package insert.

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RESULT INTERPRETATION / REPORTING

31 **Is the COVID-19 interpretative software readily available?**
(Please indicate if it comes with the equipment/device or if it has to be purchased separately.)

The GeneXpert computer and software come with the instrument

32 **Can results be transmitted directly from the system without the need to print or keep paper models?**

Results from the GeneXpert can be transferred automatically without the need to print. The GeneXpert Dx can be configured to connect to a Laboratory Information System (LIS) host computer

CROSS-CUTTING

33 **Please, as a result of the COVID-19 pandemic, can you tell us what will be the various uses of all the laboratory diagnostic equipment produced as a result of this virus?**

34 **How many manufacturing sites does have for production of this respiratory panel globally? And how would you evaluate production capacity?**

35 **Have you done any analysis of one target (1 N-gene target) vs 2 targets (2 N-gene or 1 N-gene + other)?**

36 **Does have WHO pre-qualification already?**

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CROSS-CUTTING

37 **Do you intend to submit to WHO for its Emergency Use Listing procedure?**

Yes

EUL Number:
EUL-0511-070-00

38 **Is syndromic testing being repeatedly referenced in comparison to surveillance testing, i.e. is its use case intended specifically to triage symptomatic cases in a healthcare setting?**

39 **Are there plans to introduce other diagnostic RT-PCR panels eventually? Tropical diseases, neuro, neonatal sepsis, etc.?**

40 **Does the** GeneXpert **platform have an autonomy from power supply?**

The GeneXpert instrument requires a consistent power supply

41 **Are the two options presented today available outside the US or are there are limitations on access to US diagnostics?**

42 **Any validation with conventional PCR method? Or, what gold standard test can be used for comparative study at this time?**

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CROSS-CUTTING		
43	**Is the fact of too many targets by too much for a test to use in emergencies?**	
44	**How do we predict the mutation in the target region that affects the performance of the assay?**	
45	**When E-gene only amplifies, how do you report it?**	
	SARS-CoV-2 PRESUMPTIVE POS 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	Package Insert
46	**Which of these targets are used for confirmation of SARS-CoV-2?**	
47	**Which gene target is specific for Covid-19?**	
48	**What are the implications of very high CT positive results?**	

Do you have any further comment(s) about your test device/equipment? Please provide comments in the space below.