

**QUESTIONS & ANSWERS**

**LINKS /  
REFERENCES**

**SPECIMEN MANAGEMENT**

**1 What is the specimen of choice?**

**2 List other specimens which can be used:**

**3 What is the preferred sample collection device?**

**4 List other recommended specimen collection device(s), if any:**

**5 What are the appropriate storage conditions for the collected samples?**  
(Please indicate the recommended temperature range for specimen storage and transportation.)

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**6** How long can the specimen be allowed to stand before processing?

**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.

**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.)

**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.)

**10** How stable is the device/kit after opening?  
(Please indicate if the shelf life upon opening varies with the originally assigned shelf life.)

**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.)

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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.)

**13 What is the turn-around time for the test?**

**14 Is calibration required?**

(If yes, please indicate how often, as well as where and how calibration support can be obtained.)

**15 How often is maintenance/servicing required?**

(Please indicate any maintenance/servicing support if available.)

**16 Is the device/equipment/kit a standalone or does it require complimentary lab equipment? (Mention any required accessories.)**

**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.)

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**REAGENT AND EQUIPMENT MANAGEMENT**

**18** Can kits from another company be used on your equipment?

**19** Is technical/troubleshooting support available for the device/equipment?  
(If available, please specify the type of support [online, telephone, in-person, etc.] )

**PERFORMANCE CHARACTERISTICS**

**20** What are the performance characteristics of the test for COVID-19?  
(Please provide numerical values.)

**21** What is the limit of detection of the test?

**BIOSAFETY**

**22** Is a biosafety cabinet required for the test?

**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.)

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**TEST SYSTEM / PROCEDURES / CONTROLS**

**25** What is the underlying technology? (Please specify [PCR, IgG/IgM capture, etc.] )

**26** Are there any steps in the procedure which require particular reaction conditions?  
(Please specify any temperature and humidity-sensitive incubations.)

**27** What are the indicators of a successful test?

**28** What are the indicators of a failed run?

**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.)

**30** Does the system incorporate controls? If so, how many? (Please describe.)

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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.)

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

**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?

**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 \_\_\_\_\_ platform have an autonomy from 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?

**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.