

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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SPECIMEN MANAGEMENT

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?

BIO SAFETY

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.