

## PerkinElmer ® SARS-CoV-2 Kit

### QUESTIONS & ANSWERS

### LINKS / REFERENCES

#### SPECIMEN MANAGEMENT

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

Nasopharyngeal or Oropharyngeal swab

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

Bronchoalveolar Lavage, Sputum, Plasma and Serum

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

Swab

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

Bronchoalveolar Lavage, Sputum, Dry swabs nasooropharyngeal

**5 What are the appropriate storage conditions for the collected samples?**

(Please indicate the recommended temperature range for specimen storage and transportation.)

Dependant on sample collection device used

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**SPECIMEN MANAGEMENT**

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

Dependant on sample collection device used

**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.**

Inactivation using a biosafety cabinet prior to primary sample transfer

**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, PBS can be used

**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.)**

Extraction kits are kept at room temperature and qPCR kits at -30 to -16 degrees

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

As per Expiry date.  
Once RT-PCR kits are opened they should be used within 30 days and are stable for 4 freeze thaw cycles.

**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.)**

220V/110V, 3kpa UPS

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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?**

3h30 from collection to result if it is processed immediately

**14 Is calibration required?**

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

No

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

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

1 PM per year

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

The 2 liquid handlers can be used for various liquid handling procedures and the chemagic 360 for other Nucleic acid and sample type extractions.

**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.)

The liquid handling software is easy to use and program and can be used for other chemistries as well.

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**REAGENT AND EQUIPMENT MANAGEMENT**

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

The 2 liquid handlers can do any and all standard liquid handling functions for any standard



**19 Is technical/troubleshooting support available for the device/equipment?**

(If available, please specify the type of support [online, telephone, in-person, etc.] )

We have support from South Africa and Europe available online and via telephone and once SA



**PERFORMANCE CHARACTERISTICS**

**20 What are the performance characteristics of the test for COVID-19?**

(Please provide numerical values.)

LoD 1.0 copies/uL (20 copies/reaction)

Precision (%CV) 6%

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

LoD 1.0 copies/uL (20 copies/reaction)

**BIO SAFETY**

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

For Sample inactivation Yes

**23 What biosafety level is required to perform the test or operate the device**

( )?

Once inactivated none for our instruments

**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.)**

All waste disposal should be in accordance with local regulations. The contents of the RT-PCR

kits are not considered hazardous under REACH 1907/2006. After performing the



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**TEST SYSTEM / PROCEDURES / CONTROLS**

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

RNA extraction and qPCR  
The SARS-CoV-2 Real-time RT-PCR assay uses TaqMan™-based real-time PCR technique to conduct in vitro transcription of SARS-CoV-2 RNA, DNA



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

All at Room Temperature

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

Positive and Negative controls included

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

Included controls fail

**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.)

Samples should be collected by healthcare professionals and transported appropriately.  
The RT-PCR kit should be cold-chain transported and stored at -16 to -30c. The kits are intended for use by qualified and trained clinical laboratory personal

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

Yes, per kit of 96 reactions:  
- 1x70 µL CoV2 Positive Control;  
- plasmid including virus target regions  
- 1x1000 µL CoV2 Negative Control;



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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.)

We have a simple software available to assist in calling results and it is free with our workflow. It works with the Biorad CFX instruments, Quantstudio, ABI 7500 and Azure Cielo

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

Yes

**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?**

The Janus instruments can do any liquid handling that would be done by pipettor stepper in an automated fashion.  
The chemagic 360 can do any Nucleic Acid extraction from samples like whole blood, DBS cards, Sputum, CSF, Amniotic Fluid, Urine, Stool and Tissue

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

3   
Our production is fully mature and can supply in Africa within 2 weeks of order for reagents and 2-3 weeks for instruments

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

Our qPCR kit looks at 2 genes: ORF1ab and nucleocapsid (N) genes

**36 Does PerkinElmer® SARS-CoV-2 Kit  have WHO pre-qualification already?**

Ce-IVD Approval and we also have an FDA approved qPCR kit

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**CROSS-CUTTING**

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

FDA approval in hand

**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?**

Our kit is being used for both purposes

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

NA

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

UPS Power Supply provided

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

No limitations and our options available worldwide

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

Not Applicable

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**CROSS-CUTTING**

**43** Is the fact of too many targets by PerkinElmer ® SARS-CoV-2 Kit too much for a test to use in emergencies? +

Not applicable

**44** How do we predict the mutation in the target region that affects the performance of the assay?

Not provided

**45** When E-gene only amplifies, how do you report it?

We recommend to retest

**46** Which of these targets are used for confirmation of SARS-CoV-2?

ORF1ab and nucleocapsid (N) genes

**47** Which gene target is specific for Covid-19?

ORF1ab and nucleocapsid (N) genes

**48** What are the implications of very high CT positive results?

Not provided



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

