Instructions For Use

PROmate® COVID-19 (q32) 2G Dry – D00076

96 Tests

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1. Intended purpose

PROmate® COVID-19 (q32) 2G Dry is a total workflow solution, inclusive of sample preparation, polymerase chain reaction (PCR) amplification and analysis on the genesig® q32 Real-Time PCR instrument, specifically for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This assay is based on the PROmate® COVID-19 assay which targets the ORF1ab gene, with an additional second target in a second fluorescence channel that detects the gene encoding nsp16, one of the non-structural proteins of SARS-CoV-2. Together they increase the specificity and accuracy of the PROmate® COVID-19 (q32) 2G Dry assay.

PROmate® COVID-19 (q32) 2G Dry is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal samples acquired on dry swabs. The assay can also be used on anterior nasal or combined oropharyngeal/anterior nasal swab samples that have been extracted through a magnetic bead workflow. The assay provides rapid screening of individuals with or without clinical signs associated with SARS-CoV-2 infection and aids the diagnosis of suspected COVID-19 in patients to facilitate mass population screening. The assay is intended for use with the validated genesig® q32 Real-Time PCR platform.

The PROmate® Sample Preparation Buffer V2 provides total viral inactivation. As such, there are two discrete protocols to follow for users both with and without a Class II Microbiological Safety Cabinet. This allows total flexibility for the use of the product depending on the workflow set-up of the user.

SARS-CoV-2 is generally detectable in samples during the acute phase of infection and asymptomatic infection. Positive results are indicative of the presence of SARS-CoV-2 Ribonucleic Acid (RNA). Positive results do not rule out co-infection with other bacteria or viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Positive and negative results must be interpreted alongside clinical observations, patient history and epidemiological information.

PROmate® COVID-19 (q32) 2G Dry is intended for use by trained healthcare and public health personnel specifically instructed and trained in handling SARS-CoV-2 positive samples and the techniques of Real-Time PCR and *in vitro* diagnostic procedures.

Sample test results are available to interpret in under 105 minutes using PROmate® COVID-19 (q32) Dry. This time includes the processing of the sample, the PCR set-up and run time.

2. Summary

The COVID-19 pandemic is caused by a coronavirus named SARS-CoV-2. The first human cases were identified in Wuhan, China, and reported onset of symptoms around 1st December 2019 (1). By 11th March 2020, positive cases for SARS-CoV-2 had been recognised in 110 countries and the WHO declared COVID-19 a pandemic due to the sustained risk of further spread (2). Globally the SARS-CoV-2 has infected over 500 million and has claimed over 6 million lives (3). As with most viruses, the SARS-CoV-2 also

mutates, and the changes in the genomic code have resulted in the emergence of different virus variants. These variants are suspected of having altered transmissibility rate, and impact the body's immune response and, possibly, vaccine efficacy (4). Timely and accurate diagnostics are thus crucial for clinical treatment of patients, public health decision-making and contact tracing, infection control practices and personal protective equipment (PPE) use, and avoidance of overwhelming healthcare systems.

The recent prevalence of mutations with potential biological significance within the Spike protein of SARS-CoV-2 has raised concern over the most effective targets in COVID-19 for Real-Time PCR-based diagnostic methods (5-7), suggesting the need for more than one target at a time. The PROmate® COVID-19 (q32) 2G Dry assay has been developed to target two genes to ensure the accuracy of the assay.

1. World Health Organisation (WHO). Origin of SARS-CoV-2 [Internet]. Available from: https://apps.who.int/iris/bitstream/handle/10665/332197/WHO-2019- nCoV-FAQ-Virus_origin-2020.1-eng.pdf
2. World Health Organisation (WHO). WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020 [Internet]. Available from: https://www.who.int/director-general/speeches/detail/who-director-general-sopening-remarks-at-the-media-briefing-on-covid-19 --11-march-2020
3. World Health Organisation (WHO). WHO Coronavirus Disease (COVID-19) Dashboard | WHO Coronavirus Disease (COVID-19) Dashboard [Internet]. Available from: https://covid19.who.int/
4. Wise, Jacqui. (2021) "Covid-19: The E484K mutation and the risks it poses." BMJ 372:n359. Available from https://doi.org/10.1136/bmj.n359
5. Xing Y, Li X, Gao X, Dong Q. (2020) Natural Polymorphisms Are Present in the Furin Cleavage Site of the SARS-CoV-2 Spike Glycoprotein. Front Genet. 11:1–4. Available from: https://doi.org/10.3389/fgene.2020.00783
6. Greaney AJ, Loes AN, Crawford KH, Starr TN, Malone KD, Chu HY, and Bloom JD (2021). Comprehensive mapping of mutations in the SARS-CoV-2 receptor-binding domain that affect recognition by polyclonal human serum antibodies. Cell Host & Microbe 29: 463-476. Available from: https://doi.org/10.1016/j.chom.2021.02.003
7. Andreano E, Piccini G, Licastro D, Casalino L, Johnson N V, Paciello I, et al. (2021) SARS-CoV-2 escape in vitro from a highly neutralizing COVID-19 convalescent plasma. Proc Natl Acad Sci USA 118:e2103154118. Available from: https://doi.org/10.1073/pnas.210315411

3. Test principle

Viral RNA is extracted from dry anterior nasal swabs using 'direct to PCR' technology which only includes one pipetting step. Viral RNA can also be extracted using a magnetic bead workflow from combined oropharyngeal/anterior nasal swabs stored in VTM or to concentrate the RNA extracted in the initial inactivation step with PROmate® Sample Preparation Buffer.

Using a one-step reaction, the viral RNA is reverse transcribed to cDNA and subsequently amplified using forward and reverse primers at two targets. A fluorescent labelled probe is used to detect each amplicon. The probe is based on the standard hydrolysis probe system known as TaqMan® Technology and the probes are labelled with a fluorescent reporter and quencher dyes.

During PCR cycling, the probe anneals to a specific target sequence located between the forward and reverse primers. The probe is cleaved by the 5' nuclease activity of the Taq polymerase during the extension phase of the PCR cycle, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each PCR cycle, additional reporter dye molecules are released from the probe, increasing the fluorescence intensity. Fluorescence intensity is recorded at each cycle of the PCR by the Real-Time PCR instrument.

PROmate® COVID-19 (q32) 2G Dry includes two sets of SARS-CoV-2 specific primers and probes, one set labelled with the FAM fluorophore, another with the Cy5 fluorophore. The primer/probe mix also includes primers and probes to amplify and detect an Internal Extraction Control (IEC) RNA template. This is simultaneously amplified along with any target SARS-CoV-2 RNA and provides a process control for the confirmation of a successful PCR. The IEC-specific probe is labelled with the HEX fluorophore.

The oligonucleotide primers and probes for the detection of SARS-CoV-2 were selected from two regions of the genome. Those targeting the ORF1ab genomic region are labelled with the FAM fluorophore, whereas the primers and probe targeting the gene encoding the nsp16 viral non-structural protein of SARS-CoV-2 are labelled with a Cy5 fluorophore.

PCR amplification using the included chemistry and plasticware in PROmate® COVID-19 (q32) 2G Dry is designed specifically for use on the genesig® q32 instrument. The dry format of the kit facilitates ambient transport conditions for all components, with the end user resuspending the lyophilised "cakes" just prior to running the reaction. The reagents are provided in pre-loaded magazines which will slot into the instruments to facilitate ease of use. For users operating PROmate® COVID-19 (q32) 2G Dry where turnaround requires incomplete runs, separate controls and magazines are available for total flexibility with sample numbers.

PROmate® COVID-19 (q32) 2G Dry is designed to preclude the need for a Class II Microbiological Safety Cabinet, if required. By enabling the release of viral RNA from the sample directly in closed tubes without creating aerosols, PROmate® COVID-19 (q32) 2G Dry guarantees protection of the operator and prevents contamination of the work area. The use of PROmate® COVID-19 (q32) 2G Dry with or without Class II Microbiological Safety Cabinet depends upon the protocol followed. For further information, please refer to Section 8.

4. Materials

The reagents necessary for each run come in two different packs; a box (Pack 1) and a pouch (Pack 2), both shipped ambient.

PROmate® COVID-19 (q32) 2G Dry Pack 1 contains 6 bags (3 foils and 3 ziplock bags) and should be stored at ambient temperature. The contents are shown in the table below.

Pack 1 PROmate® COVID-19 (q32) 2G Dry Box (3 x foil pouches and 3 x clear plastic ziplock bags)

Reagent label	Number of items per 32 test pack	Volume (µl per vial)
PROmate® RNase inhibitor with IEC	30	n/a
PROmate® Sample Prep Buffer V2 BLUE CAP	30	1000
QR code labels	30	n/a

PROmate® COVID-19 (q32) 2G Dry Pack 2 should be stored frozen (-25°C to -15°C). Upon opening, the pack contains 3 PROmate® COVID-19 (q32) 2G Dry Positive Controls, 3 PROmate® COVID-19 (q32) 2G Dry q32 magazines (including lids), 6 PROmate® Master mix resuspension buffer, 1 PROmate® positive control resuspension buffer and 3 negative control solutions as per the table below.

Pack 2 PROmate® COVID-19 (q32) 2G Dry Pouch (3 x gold foil pouches with positive control, 3 x white foil pouches with magazine, 1 x ziplock bag of resuspension buffers, 1 x ziplock bag of negative control and 1 x blue foil pouch with spare Master mix tubes)

Reagent label	Number of items per 32 test pack	Volume (µl per vial)
PROmate® COVID-19 2G Dry Pos Control	1	n/a
PROmate® COVID-19 2G Dry Master mix q32 magazine	1	n/a
PCR tube lids	32	n/a
PROmate® Master mix Resuspension Buffer WHITE CAP	2	500
PROmate® Pos Ctrl Resuspension Buffer BLACK CAP	1 tube supplied for all positive controls	200
PROmate® 2G Negative Control Solution V2 RED CAP	1	50
PROmate® COVID-19 2G Dry Spare mmix q32 tubes	3 tubes supplied as spares for all test packs	n/a

5. Storage

The PROmate® COVID-19 (q32) 2G Dry assay is shipped at ambient temperature.

Pack 1 must be stored in the original packaging at ambient temperatures upon arrival and will remain stable for up to 12 months when stored at 25°C.

Pack 2 must be stored in the original packaging at -15 to -25°C upon arrival and will remain stable for up to 3 months when stored at -20°C.

If the kit's protective packaging is damaged upon receipt or the tamper proof seal has been compromised, please contact Primerdesign for instructions.

Attention should be paid to the "use by" date specified on the pack label and individual tube labels. On this date, the kit should be discarded following the disposal instructions in Section 11.

6. Warnings

1. Please consult the Safety Data Sheet (SDS) before using this kit which is available on request.
2. Please comply with laboratory codes of practice.
3. Handle all specimens as if infectious using safe laboratory procedures. Specimen processing should be performed in accordance with national biological safety regulations.
4. Perform all manipulations of potential live virus samples within a class II (or higher) biological safety cabinet (refer to the guidance detailed in Section 7).
5. Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
6. Use personal protective equipment such as (but not limited to) gloves, eye protection and lab coats when handling kit reagents while performing this assay and handling materials including samples, reagents, pipettes and other equipment and reagents.

Any serious incident that has occurred in relation to this device should be reported by the user to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

7. Specimen collection and handling

For the direct to PCR workflow this product is intended for use with dry anterior nasal swabs only. Use of media not supplied as part of this product will impact the detection limit of the device.

For an extracted workflow, this product is intended for use with combined oropharyngeal/anterior nasal swabs, collected and stored in VTM. Alternatively, RNA can also be extracted from an anterior nasal swab collected and inactivated in the PROmate® Sample Preparation Buffer.

Samples that present with obvious blood or other particulate matter are NOT compatible with PROmate® COVID-19 (q32) 2G Dry and should be discarded.

Sampling should be conducted with the correct swab type and collected following the correct sampling technique. CDC guidance on collection of anterior nasal swabs can be found here: https://www.cdc.gov/coronavirus/2019-ncov/testing/How-To-Collect-Anterior-Nasal-Specimen-for-COVID-19.pdf

Inadequate or inappropriate clinical sample collection, storage and transport are likely to yield false test results. Training of personnel in clinical sample collection is highly recommended. CLSI MM13 (Clinical and Laboratory Standards Institute) may be referenced as an appropriate resource.

Dry anterior nasal swab samples should be collected and placed in a clean, dry, sterile transport tube prior to testing.

Combined oropharyngeal/anterior nasal swab samples should be collected and stored in VTM prior to extraction and assay.

For dry swabs for use inside a Class II Microbiological Safety Cabinet, swab samples must be transported within 24 hours and tested as soon as possible after collection. If this is not possible, the following storage recommendations should be followed:
If the swab is stored at 2-8°C, the clinical sample must be tested within 72 hours.
If testing cannot be conducted within 72 hours, the swab clinical sample should be frozen at -70°C or colder until testing is conducted.

Once dry anterior nasal swab samples have been resuspended and inactivated in PROmate® sample preparation buffer V2, they must be tested within five hours if kept at room temperature. If this is not possible, resuspended samples can be stored at 4°C for up to 72 hours, or frozen at -80°C for up to 9 days. Frozen samples should be added to a resuspended PROmate® PCR reaction tube and assayed as soon as possible after thawing.

For further guidance on clinical samples please refer to the following:
UK Government guidance on handling and processing potential COVID-19 samples in laboratories:
https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens

World Health Organization Interim guidance on laboratory biosafety from 28 January 2021: Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases: https://www.who.int/publications/i/item/WHO-WPE-GIH-2021C.1

Interim Guidelines for Collecting, Handling and Testing Clinical Samples from Persons under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

The PROmate® Sample Preparation Buffer V2 contains Triton X-100 Reduced (Triton X-100 replacement) and has been utilised for the inactivation of SARS-CoV-2 by Public Health England. Therefore, samples should be handled according to these revised national guidelines for sample management prior to inactivation.

Follow clinical sample collection instructions by device manufacturer for proper collection methods.

Swab samples should be collected using swabs with a synthetic tip, such as nylon or Dacron® and with an aluminium or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.

8. Assay procedure

8.1 Equipment preparation

- Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use.
- Decontamination agents such as 10% bleach should be used to minimise the risk of nucleic acid contamination.

8.2 Assay set up

The following instructions should be adhered to when handling clinical samples and reagents during procedure set-up with PROmate® COVID-19 (q32) 2G Dry in order to ensure consistent, accurate results:

- Do not handle reaction tubes by their base as this may affect optical reading. Reaction tubes should be held by the rim/lid to avoid any contact with the sides of the tube.
- Tubes must not rest directly on the workbench; use racks for holding tubes wherever possible.
- Prior to loading samples and positive control templates (PCTs) and prior to running on the instrument ensure the contents of the tubes are at the bottom by performing visual checks, flicking to remove bubbles and centrifuging when necessary. Failure to do so could result in errors in signal interpretation by the instrument.
- If centrifuging a PROmate magazine, ensure that all tubes are firmly seated in the magazine, and all lids are sealed. A spin of 1 minute at 300 x *g* is usually sufficient to remove bubbles.
- Before opening the positive control foil pouch, visually inspect for any signs that it is already open. If there is evidence of damage to the bag, DO NOT OPEN and use a replacement positive control to avoid contamination.
- The positive control should be processed separately to all other samples to reduce the potential for contamination of samples and the negative control.
- Visually inspect all reaction tubes for air bubbles prior to running PROmate® COVID-19 (q32) Dry. Failure to do so could result in errors in signal interpretation by the instrument.

For total user flexibility there are two separate workflows for using PROmate® COVID-19 (q32) Dry:

- Processing of samples outside of a Class II Microbiological Safety Cabinet – protocol in Section 8.3
- Processing of samples inside a Class II Microbiological Safety Cabinet– protocol in Section 8.4.

Please follow the appropriate protocol for your workflow stream. It is important that the correct workflow is followed to ensure user safety and total viral inactivation prior to PCR set-up.

8.3 Dry anterior nasal swab sample processing outside of a Category II Biosafety Cabinet

Sample collection

a. Add one lyophilised RNase inhibitor with IEC and red bead to the Sample Preparation Buffer tube to be used. The bead within is coloured red; this provides easy identification that the inhibitor has been added. Vortex for 10 s and leave for at least five minutes before adding the swab.
b. Place dry anterior nasal patient swab in assigned Sample Preparation Buffer tube and break to fit inside the tube (optional: use scissors to cut swab to an appropriate length, if necessary). Close lid with swab inside. If using scissors, ensure they are decontaminated with 70% alcohol (ethanol or isopropanol) in between each sample.
c. Once all samples have been resuspended, leave the Sample Preparation Buffer tubes at room temperature for at least 5 minutes. This is necessary for total SARS-CoV-2 inactivation.
d. The sample resuspension and inactivation (steps a-c) must take place at the point of sample taking.

Sample processing

e. Label the sample appropriately to ensure patient sample traceability.
f. Repeat step (e) for all patient samples to be processed.
g. Open frozen PROmate® Pack 2 and defrost:
    - PROmate® COVID-19 2G Dry Master mix q32 Magazine with PCR reaction tubes. Ensure dried content is at the bottom of the tubes.
    - PROmate® Master mix resuspension buffer (white lid - two tubes needed for 30 samples)
    - PROmate® COVID-19 2G Dry Positive control tube. DO NOT open pouch.
    - PROmate® Positive control resuspension buffer (black lid)
    - PROmate® 2G Negative control solution V2 (red lid).
h. Vortex each Sample Preparation Buffer tube thoroughly to release swab contents into solution.
i. Once ambient incubation is complete, remove the foil on the designated PCR reaction tube and resuspend the dried “cake” with 15 µl of PROmate® Master mix Resuspension Buffer (white lid). Dispense the liquid on the internal wall of the tube and the cake will dissolve easily upon contact. Further mixing is not necessary. A pipette capable of multidispensing can be used at this point to save time.
j. Transfer 5 µl of the relevant patient Sample Preparation Buffer tube content into the designated PCR reaction tube. Seal with provided cap.
k. Repeat steps (i) and (j) for all samples.
l. Add 5 µl of the Negative Control Solution (red lid) into the PCR reaction negative control tube (position N) and seal.
m. Inspect the Positive Control pouch, and check packaging has not been previously compromised. Open, remove and inspect the Positive Control tube, and check the seal has not been previously compromised. Inspect the contents to confirm the presence of a single dried pellet at the base of the tube. If pellet is not visible or is highly fragmented, contact technical support for advice.
n. Remove the foil from the positive control and resuspend with 20 µl of the PROmate® Positive Control Resuspension Buffer (black lid), Dispense the liquid on the internal wall of the tube and the cake will dissolve easily upon contact. Further mixing is not necessary. Seal immediately following resuspension with provided cap, and centrifuge to ensure contents are at the bottom of the tube.
o. Place in position “P” of the magazine. We advise changing gloves at this point to ensure no transfer of positive control material to other samples or the instrument.
p. Flick the magazine to remove any bubbles or use microcentrifuge.
q. Place magazine in correct orientation to genesig® q32. and ensure all tubes are seated properly in the magazine, confirmed with an audible `click` sound. When operating with a partial run (i.e., NOT complete magazines), use blank 0.1 ml PCR tubes to fill gaps and balance the lid on the instrument.
r. Start the run protocol using the provided template file.

8.4 Dry anterior nasal swab sample processing with a Category II Biosafety Cabinet

Sample collection and processing

a. Add one lyophilised RNase inhibitor with IEC and red bead to each Sample Preparation Buffer tube to be used, close and invert to mix. The bead within is coloured red; this provides easy identification that the inhibitor has been added. Vortex for 10 s and leave for at least five minutes before adding the swab.

b. Inside of the category II class biosafety cabinet, place dry anterior nasal patient swab in assigned Sample Preparation Buffer tube and twirl to release the swab contents into suspension. Upon removal of swab, squeeze head against side of tube to release liquid. Close lid and vortex thoroughly.
c. Label the sample appropriately to ensure patient sample traceability.
d. Repeat steps (b) and (c) for all patient samples to be processed.
e. Once all samples have been resuspended, leave the Sample Preparation Buffer tubes at room temperature for at least 5 minutes. This is necessary for total SARS-CoV-2 inactivation.
f. Open frozen PROmate® Pack 2 and defrost:
    - PROmate® COVID-19 2G Dry Master mix q32 Magazine with PCR reaction tubes. Ensure dried content is at the bottom of the tubes.
    - PROmate® Master mix resuspension buffer (white lid - two tubes needed for 30 samples)
    - PROmate® COVID-19 2G Dry Positive control tube. DO NOT open pouch.
    - PROmate® Positive control resuspension buffer (black lid)
    - PROmate® 2G Negative control solution V2 (red lid).
g. Vortex each Sample Preparation Buffer tube thoroughly to release swab contents into solution.
h. Once ambient incubation is complete, remove the foil on the designated PCR reaction tube and resuspend the dried “cake” with 15 µl of PROmate® Master mix Resuspension Buffer (white lid). Dispense the liquid on the internal wall of the tube and the cake will dissolve easily upon contact. Further mixing is not necessary. A pipette capable of multi-dispensing can be used at this point to save time.
i. Transfer 5 µl of the relevant patient Sample Preparation Buffer tube content into the designated PCR reaction tube. Seal with provided cap.
j. Repeat step (h) and (i) for all samples.
k. Add 5 µl of the Negative Control Solution (red lid) into the PCR reaction negative control tube (position N) and seal.
l. Inspect the Positive Control pouch, and check packaging has not been previously compromised. Open, remove and inspect the Positive Control tube, and check the seal has not been previously compromised. Inspect the contents to confirm the presence of a single dried pellet at the base of the tube. If pellet is not visible or is highly fragmented, contact technical support for advice.
m. Remove the foil from the positive control and resuspend with 20 µl of the PROmate® Positive Control Resuspension Buffer (black lid), Dispense the liquid on the internal wall of the tube and the cake will dissolve easily upon contact. Further mixing is not necessary. Seal immediately following resuspension with provided cap, and centrifuge to ensure contents are at the bottom of the tube.
n. Place in position “P” of the magazine. We advise changing gloves at this point to ensure no transfer of positive control material to other samples or the instrument.
o. Flick the magazine to remove any bubbles or use microcentrifuge.
p. Place magazine in correct orientation to genesig® q32 and ensure all tubes are seated properly in the magazine, confirmed with an audible `click` sound. When operating with a partial run (i.e., NOT complete magazines), use blank 0.1 ml PCR tubes to fill gaps and balance the lid on the instrument.
q. Start the run protocol using the provided template file.

8.5 Extracted sample workflow (combined oropharyngeal/anterior nasal swabs in VTM)

While the PROmate® workflow is designed for direct to PCR inactivation of dry swab samples, the PCR reaction can also be used on samples eluted from a magnetic bead extraction system such as the exsig® Mag kit.

a. Collect the combined oropharyngeal/anterior nasal swab in 1-2 ml of VTM.
b. Label the sample appropriately to ensure patient sample traceability.
c. Repeat steps (a) and (b) for all patient samples to be processed.
d. In a Category II Biosafety Cabinet, pipette 1 ml of the VTM into a fresh tube (or as close to this volume as possible as the swab may have taken on some of the VTM liquid).
e. Add one lyophilised RNase inhibitor with IEC and red bead to the VTM, and vortex briefly to ensure mixing. This will provide the IEC to monitor the extraction of the sample.
f. Proceed to extraction as quickly as possible to ensure IEC integrity is maintained.
g. Follow your usual extraction workflow, using 200 µl of the VTM plus IEC, and eluting in 50 µl.
h. Open frozen PROmate® Pack 2 and defrost:
    - PROmate® COVID-19 2G Dry Master mix q32 Magazine with PCR reaction tubes. Ensure dried content is at the bottom of the tubes.
    - PROmate® Master mix resuspension buffer (white lid - two tubes needed for 30 samples)

- PROmate® COVID-19 2G Dry Positive control tube. DO NOT open pouch.
- PROmate® Positive control resuspension buffer (black lid)
- PROmate® 2G Negative control solution V2 (red lid).

i. Remove the foil on the designated PCR reaction tube and resuspend the dried "cake" with 15 µl of PROmate® Master mix Resuspension Buffer (white lid). Dispense the liquid on the internal wall of the tube and the cake will dissolve easily upon contact. Further mixing is not necessary. A pipette capable of multi-dispensing can be used at this point to save time.
j. Transfer 5 µl of the relevant patient eluate into the designated PCR reaction tube. Seal with provided cap.
k. Repeat step (i) and (j) for all samples.
l. Add 5 µl of the Negative Control Solution (red lid) into the PCR reaction negative control tube (position N) and seal.
m. Inspect the Positive Control pouch, and check packaging has not been previously compromised. Open, remove and inspect the Positive Control tube, and check the seal has not been previously compromised. Inspect the contents to confirm the presence of a single dried pellet at the base of the tube. If pellet is not visible or is highly fragmented, contact technical support for advice.
n. Remove the foil from the positive control and resuspend with 20 µl of the PROmate® Positive Control Resuspension Buffer (black lid), Dispense the liquid on the internal wall of the tube and the cake will dissolve easily upon contact. Further mixing is not necessary. Seal immediately following resuspension with provided cap, and centrifuge to ensure contents are at the bottom of
o. Place in position "P" of the magazine. We advise changing gloves at this point to ensure no transfer of positive control material to other samples or the instrument.
p. Flick the magazine to remove any bubbles or use microcentrifuge.
q. Place magazine in correct orientation to genesig® q32 and ensure all tubes are seated properly in the magazine, confirmed with an audible `click` sound. When operating with a partial run (i.e., NOT complete magazine), use blank 0.1 ml PCR tubes to fill gaps and balance the lid on the instrument.
r. Start the run protocol using the provided template file.

NB. An anterior nasal swab sample inactivated in PROmate® Sample Preparation Buffer (SPB) as per workflows 8.3 (steps a-e) and 8.4 (steps a-e) can be further extracted using a magnetic bead workflow (such as exsig® Mag) as per the above instructions. For such a sample, start at step 8.5 (f) with 200 µl of sample in SPB plus RNase inhibitor and IEC bead.

8.6 Programming the Real-Time PCR instrument

Please refer to the following manual for additional information on using the instrument: genesig® q32 (Primerdesign™, Novacyt, software version 1.6 or later).

On the q32 software, select "New" and the cycling conditions are provided in the software assay module "2G PROmate testing kit", with the user selecting "Dry" when prompted. Input further information on Sample IDs/Tests as per the genesig® q32 user manual.

8.7 Acceptance criteria of controls

The q32 software uses the following criteria to verify the success of the run as indicated by the status "Pass" in the control wells:

- Negative Control is free from amplification in the FAM channel, and any amplification in the HEX channel is Cq >35.
- PCT produces a Cq of between 14-25 in both the FAM and Cy5 channels.

If these criteria are not satisfied, the software will report "Reaction Failure" and/or "Contamination". Please contact Technical Support for further guidance.

8.8 Interpretation of results

If all the control acceptance criteria are fulfilled, then each sample will be assessed by the software with the below criteria using PROmate® COVID-19 (q32) 2G Dry with the genesig® q32, to give a status for each sample.

Those samples which are given "Inconclusive" status should be rerun.

ORF1ab FAM (465-510)	nsp16 Cy5 (618-660)	IEC HEX (533-580)	Status given
Cq <37.83*	Cq +	Cq +/-	Positive
Cq <37.83	Cq -	Cq +/-	Positive
Cq - or Cq ≥37.83	Cq +	Cq +/-	Positive
Cq - or Cq ≥37.83	Cq -	Cq ≤35	Negative

Cq - or Cq ≥37.83	Cq -	Cq - or Cq >35	Inconclusive**

***Limit of blank testing established that FAM amplification >37.83 should be concluded as negative (see Section 9.1.4)**
****If the sample IEC HEX Cq is within 5 Cq of the NTC HEX Cq, the sample will be called as "IEC Contamination"**

8.9 Limitations of the procedure

- The procedures in this IFU must be followed as described. Any deviations may result in assay failure or erroneous results.
- Good laboratory practice is required to ensure the performance of the kit. Components should be monitored for contamination and any components thought to have become contaminated should be discarded as standard laboratory waste in a sealed pouch or zip-lock plastic bag.
- As with any molecular test, mutations within the target sequence of SARS-CoV-2 could affect the PROmate® COVID-19 (q32) 2G Dry primer and/or probe binding, resulting in failure to detect the virus.
  - False negative results may be caused by:
  - Unsuitable collection, handling and/or storage of samples.
  - Sample outside of viremic phase.
  - Failure to follow procedures in this handbook.
- False positive results may be caused by:
  - Unsuitable handling of samples containing high concentration of SARS-CoV-2 viral RNA or Positive Control Template.
  - Unsuitable handling of amplified product.
- All results should be interpreted by a healthcare professional in the context of patient medical history and clinical symptoms.
- This test cannot rule out diseases caused by other pathogens.
- A negative result for any PCR test does not conclusively rule out the possibility of infection with SARS-CoV-2.

9. Analytical performance

9.1 Analytical sensitivity (limit of detection)

The limit of detection (LoD) is defined as the lowest concentration of analyte that can be reliably detected with 95% confidence. Briefly, wild type SARS-CoV-2 whole genome template from heat-inactivated virus was obtained from the American Type Culture Collection (ATCC) and quantified prior to dilution. These dilutions were contrived into negative clinical samples and subjected to three different workflows – the direct to PCR workflow, and extraction via magnetic beads (exsig® Mag, using the KingFisher™ Flex platform from ThermoFisher) from either viral transport medium (VTM) or the PROmate® sample preparation buffer (SPB). Extraction started with 200 µl of the medium/buffer and samples were eluted in 50 µl. In all studies at least five donors (determined to be SARS-CoV-2 negative by lateral flow test) provided swab samples of the types indicated.

A tentative LoD was obtained on three consecutive days, with five replicates at each contrivance level tested. Once a tentative LoD had been established (the concentration at which all five replicates gave a positive detection result), the LoD was verified by testing further contrivance levels around this concentration, with at least 20 replicates tested at each level.

For each workflow the detection rate was determined, both overall and within each SARS-CoV-2 target channel. The Cq values shown in the table below were obtained from the Advanced User mode of the genesig® q32 software.

9.1.1 Verification of the LoD with anterior nasal swabs – direct to PCR

Copies in the original sample (c/ml)	Overall detection rate %	FAM (ORF1ab)		Cy5 (nsp16)		HEX (IEC)
		Channel Detection rate %	Mean Cq (STDEV)	Channel Detection rate %	Mean Cq (STDEV)	Mean Cq (STDEV)
3000	100	100	35.88 (0.81)	50	36.90 (0.91)	23.74 (0.61)
2000	**100**	**90**	**35.97 (0.73)**	**50**	**37.03 (0.69)**	**23.63 (0.27)**
1000	70	50	36.40 (0.89)	40	37.31 (0.60)	23.44 (0.31)
600	80	65	36.25 (0.59)	30	36.62 (0.64)	23.17 (0.32)
200	30	25	37.02 (0.58)	10	38.42 (0.86)	23.49 (0.28)

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The data above demonstrates that the LoD for PROmate® COVID-19 (q32) 2G Dry when using the direct to PCR workflow from anterior nasal swabs was 2000 copies/ml in the sample (10 copies/reaction in the PCR).

9.1.2 Verification of the LoD with combined oropharyngeal/anterior nasal swabs – extraction from VTM

Copies in the original sample (c/ml)	Overall detection rate %	FAM (ORF1ab)		Cy5 (nsp16)		HEX (IEC)
		Channel Detection rate %	Mean Cq (STDEV)	Channel Detection rate %	Mean Cq (STDEV)	Mean Cq (STDEV)
600	100	100	34.76 (0.79)	95	36.40 (1.00)	21.93 (0.44)
400	100	94.74	34.94 (0.64)	100	35.41 (1.04)	22.27 (0.38)
200	100	100	36.14 (0.78)	100	36.25 (1.04)	22.00 (0.19)
100	**95**	**75**	**37.03 (0.88)**	**80**	**37.06 (0.76)**	**22.26 (0.25)**
50	55	40	37.05 (0.62)	25	36.94 (0.54)	20.77 (0.17)

The data above demonstrate that the LoD for PROmate® COVID-19 (q32) 2G Dry when using combined oropharyngeal/anterior nasal swabs samples extracted from viral transport medium (VTM) was 100 copies/ml in the sample (2 copies/reaction in the PCR).

9.1.3 Verification of the LoD with anterior nasal swabs – extraction from SPB

Copies in the original sample (c/ml)	Overall detection rate %	FAM (ORF1ab)		Cy5 (nsp16)		HEX (IEC)
		Channel Detection rate %	Mean Cq (STDEV)	Channel Detection rate %	Mean Cq (STDEV)	Mean Cq (STDEV)
300	100	95	36.23 (0.91)	85	36.35 (0.79)	21.72 (0.51)
250	**95**	**75**	**36.33 (0.85)**	**85**	**36.59 (1.57)**	**21.57 (0.38)**
100	90	55	37.59 (1.41)	65	37.4 (0.47)	21.93 (0.34)
50	50	30	38.83 (0.73)	40	37.68 (1.01)	21.63 (0.23)

The data above demonstrate that LoD for PROmate® COVID-19 (q32) 2G Dry when using anterior nasal swabs samples extracted from Sample Preparation Buffer (SPB) was 250 copies/ml in the sample (5 copies/reaction in the PCR).

9.1.4 Limit of Blank

The Limit of Blank (LoB) is the highest apparent analyte concentration that is expected to be detected in any channel only when replicates of blank sample containing no analyte are tested. Positive amplification of Cq higher than the LoB in such channels will be concluded as negative. The LoB was determined by analysing 90 negative samples with PROmate® COVID-19 (q32) 2G Dry and the Cq values generated were used to determine what level of amplification could be considered insignificant. The LoB of the assay is 37.83 Cq in the FAM channel (ORF1ab target) and any Cq higher than this value in this channel only should be concluded as negative.

9.2 Analytical specificity (Cross-reactivity)

The objective of this study is to assess the analytical specificity-inclusivity and exclusivity of the PROmate® COVID-19 (q32) 2G Dry assay. Analytical specificity was evaluated by 'wet' testing related pathogens and pathogens that are likely to be present in the clinical specimen. The study identified the homology between the primers/probe of the assay and the pathogens.

9.2.1 Latest *in silico* Specificity Analysis

To ensure the COVID-19 primer/probe remain specific to detect SARS-CoV-2 genomes, Primerdesign's bioinformaticians review daily the SARS-CoV-2 sequence submissions on the GISAID EpiCoV database. As of 8th of June 2022, *in silico* analysis confirms the COVID-19 assay primers and probe still show 99.8% and 99.9% identity with the 9,859,534 and 9,935,921 full length, good quality

SARS-CoV-2 sequences at the ORF1ab and nsp16 genes respectively. These include variants identified as Variants of Concern (VoC) and Variants under Investigation (VuI) including the Delta and Omicron variants as well as variants that carry the N501Y, E484K and L452R mutations.

9.2.2 Wet testing

To assess specificity, a panel of organisms which could be present within relevant clinical matrices was procured. The panel used was the NATtrol ™ Respiratory Verification Panel. The samples from these panels are representative of true clinical human specimens and triplicate extracts from the samples were evaluated by the PROmate® COVID-19 (q32) 2G Dry assay. Eluates were tested after extraction using the exsig® Mag kit on a KingFisher™ Flex platform (ThermoFisher). Amplification was analysed using the genesig® q32 software, which determined sample status as positive, negative or inconclusive with the sample Cq values obtained from the Advanced User mode.

	FAM (ORF1ab)		Cy 5 (nsp16)		HEX (IEC)	
Sample	**Positive calls**	**Mean Cq**	**Positive calls**	**Mean Cq**	**Positive calls**	**Mean Cq**
Influenza AH1	0/3	N/A	0/3	N/A	3/3	23.65
Influenza AH3	0/3	N/A	0/3	N/A	3/3	23.99
Influenza A H1N1pdm	1/3	37.53	0/3	N/A	3/3	23.55
Influenza B	0/3	N/A	0/3	N/A	3/3	23.79
Metapneumovirus 8	0/3	N/A	0/3	N/A	3/3	23.83
RSV A	0/3	N/A	0/3	N/A	3/3	23.45
Rhinovirus 1A	0/3	N/A	0/3	N/A	3/3	24.04
Parainfluenza 1	0/3	N/A	0/3	N/A	3/3	23.22
Parainfluenza 2	0/3	N/A	0/3	N/A	3/3	23.80
Parainfluenza 3	0/3	N/A	0/3	N/A	3/3	23.50
Parainfluenza 4	0/3	N/A	0/3	N/A	3/3	23.96
Adenovirus 3	0/3	N/A	0/3	N/A	3/3	23.57
Coronavirus NL64	0/3	N/A	0/3	N/A	3/3	23.92
Coronavirus 229E	1/3	35.79	0/3	N/A	3/3	23.85
Coronavirus OC43	0/3	N/A	0/3	N/A	3/3	23.94
Coronavirus HKU-1	0/3	N/A	0/3	N/A	3/3	23.74
M. pneumoniae	0/3	N/A	0/3	N/A	3/3	23.55
C. pneumoniae	0/3	N/A	0/3	N/A	3/3	23.80
B. pertussis	0/3	N/A	0/3	N/A	3/3	23.75
Panel Negative Control	1/3	37.78	0/3	N/A	3/3	23.48
NEC 1	0/1	N/A	0/1	N/A	1/1	22.08
NEC 2	0/1	N/A	0/1	N/A	1/1	22.19
NEC 3	0/1	N/A	0/1	N/A	1/1	22.30
NEC 4	0/1	N/A	0/1	N/A	1/1	21.97
NEC 5	0/1	N/A	0/1	N/A	1/1	22.43

Influenza A H1N1pdm and Coronavirus 229E exhibited amplification in 1/3 wells in the initial run. Although this was likely due to environmental contamination (as indicated by one of the three replicates of the Panel Negative Control amplifying), both the panel members, the Panel Negative Control and the NEC were re-extracted and 20 replicates of each were run to confirm this was not due to kit cross-reactivity (see Table below)

	FAM (ORF1ab)		Cy 5 (nsp16)		HEX (IEC)	
Sample	**Positive calls**	**Mean Cq**	**Positive calls**	**Mean Cq**	**Positive calls**	**Mean Cq**
Influenza A H1N1pdm	0/20	N/A	0/20	N/A	20/20	24.23
Coronavirus 229E	0/20	N/A	0/20	N/A	20/20	24.13
Panel Negative Control	1/20	36.83	0/20	N/A	20/20	24.02

NEC	0/20	N/A	0/20	N/A	20/20	22.93

On re-running the two-panel members at a higher replicate number, the hit rate was 0/20 for these samples, indicating that the late amplification observed in the initial run was not representative of cross-reactivity. In summary, these results show that the PROmate® COVID-19 (q32) 2G Dry assay exhibits no cross-reactivity with any of the clinically relevant organisms/pathogens tested.

9.3 Precision (repeatability and reproducibility)

The objective of this study is to determine the precision (reproducibility and repeatability) of the PROmate® COVID-19 (q32) 2G Dry assay. Repeatability was measured by analysing within-run variation of replicates. Reproducibility was measured by three variables: inter-day, inter-instrument and inter-operator variability.

Briefly, three different contrivance levels of the ATCC heat-inactivated wild type SARS-CoV-2 whole genome were used, contrived in negative anterior nasal swab clinical samples, taken through the direct to PCR workflow:

- High viral load (15-fold Limit of Detection (LoD)) – 30,000 copies/ml in the sample
- Medium viral load (10-fold LoD) – 20,000 copies/ml in the sample
- Low viral load (5-fold LoD) – 10,000 copies/ml in the sample

Three different batches of the PROmate® COVID-19 (q32) 2G Dry kit were tested, with 10 replicates at each contrivance level assayed. Cq values were obtained from the Advanced User mode of the q32 software, which allowed establishment of Mean Cq and Standard Deviation. These values are then used to calculate the % Coefficient of Variance (CV) for each contrivance level in the different scenarios. As evidenced in the tables below, all comparisons always gave a CV value of less than 10%.

Summary of repeatability and reproducibility for the PROmate® COVID-19 (q32) 2G Dry assay (FAM, Cy5 and HEX channels), batch 1.

		Coefficient of variance (%) for PROmate® COVID-19 (q32) 2G Dry – Batch 1			
Sample concentration (copies/ml)	**Target channel**	**Repeatability**	**Inter-Instrument**	**Inter-operator**	**Inter-day**
30,000	FAM	0.41	0.48	0.46	4.18
	Cy5	0.92	0.93	1.24	3.83
	HEX	0.79	1.05	2.02	10.51
20,000	FAM	0.45	0.73	0.66	3.03
	Cy5	1.04	1.18	1.20	2.65
	HEX	1.04	0.80	1.81	7.94
10,000	FAM	0.97	1.04	0.88	2.43
	Cy5	1.01	1.26	1.07	2.54
	HEX	0.92	0.96	2.56	6.75

Summary of repeatability and reproducibility for the PROmate® COVID-19 (q32) 2G Dry assay (FAM, Cy5 and HEX channels), batch 2.

		Coefficient of variance (%) for PROmate® COVID-19 (q32) 2G Dry – Batch 2			
Sample concentration (copies/ml)	**Target channel**	**Repeatability**	**Inter-Instrument**	**Inter-operator**	**Inter-day**
30,000	FAM	1.12	1.15	1.12	1.28
	Cy5	1.21	1.07	1.20	1.31
	HEX	0.68	1.08	0.62	4.11
20,000	FAM	0.69	0.81	0.74	1.15
	Cy5	1.15	1.09	1.23	1.34
	HEX	2.63	2.26	2.43	5.03

10,000	FAM	1.16	1.07	0.99	1.45
	Cy5	3.10	2.73	2.65	2.81
	HEX	1.39	1.88	2.00	4.03

Summary of repeatability and reproducibility for the PROmate® COVID-19 (q32) 2G Dry assay (FAM, Cy5 and HEX channels), batch 3.

		Coefficient of variance (%) for PROmate® COVID-19 (q32) 2G Dry – Batch 3			
Sample concentration (copies/ml)	**Target channel**	**Repeatability**	**Inter-Instrument**	**Inter-operator**	**Inter-day**
30,000	FAM	2.20	2.83	4.74	2.19
	Cy5	2.24	2.40	3.04	2.01
	HEX	2.66	5.00	6.98	3.90
20,000	FAM	0.82	1.38	4.53	0.84
	Cy5	1.94	2.33	2.91	1.76
	HEX	2.50	3.33	7.12	4.03
10,000	FAM	1.70	1.75	2.08	1.42
	Cy5	2.86	2.50	3.47	2.21
	HEX	3.68	3.15	9.16	2.82

9.4 Accuracy (trueness and precision)

The objective of this study was to determine the diagnostic accuracy of the PROmate® COVID-19 (q32) 2G Dry assay through the generation of three key statistics.

- Positive Percentage Agreement (PPA)
- Negative Percentage Agreement (NPA)
- Overall Percentage Agreement (OPA)

Percentage agreement was generated by conducting single-blind randomised testing using PROmate® COVID-19 (q32) 2G Dry and comparing the results to the contrivance status of either negative samples or samples contrived with heat-inactivated wild type SARS-CoV-2 whole genome (ATCC) at 3 x LoD. The samples were anterior nasal swab samples from SARS-CoV-2 negative donors, taken through the direct-to PCR workflow.

The overall positive and negative agreement was calculated by comparing test results with the recorded contrivance status.

		Contrived Sample Status		
		Positive	**Negative**	**Total**
PROmate® COVID-19 (q32) 2G Dry assay	**Positive**	87	6	93
	Negative	1	83	84
	Total	88	89	177

Positive Percentage Agreement (PPA)	Negative Percentage Agreement (NPA)
98.86% (95% CI 93.84% to 99.80%)	93.26% (95% CI 86.06% to 96.87%)
Overall Percentage Agreement (OPA)	
96.05% (95% CI 92.06% to 98.07%)	

9.5 Interfering substances

The potential interferants used in this study were selected based on common interfering substances found in anterior nasal and oropharyngeal specimens. Each potential interferant was tested at a therapeutic concentration and a toxic/test concentration as determined from literature research or the CLSI guidelines (EP07-A2). Each solvent used for these substances was also tested to ensure it was not the cause of any interference. Swab samples were obtained from SARS-CoV-2 negative donors and either

uncontrived (negative samples) or contrived with SARS-CoV-2 whole genome RNA (ATCC). Samples were either an anterior nasal sample, processed through the direct to PCR workflow, or a combined oropharyngeal/anterior nasal sample, extracted from VTM. A contrivance level of 3 x the LoD of the sample type/workflow was used.

Positive or negative sample status was called as per the "Interpretation of Results" section of this IFU. Thus if a positive sample became called negative or inconclusive this would be deemed as interference, and conversely if a negative sample exhibited amplification in the FAM or Cy5 channel, this would also be deemed interference. Seven positive samples and seven negative samples were tested with each interferant and the respective solvents.

In summary, the data below show that Oseltamivir Phosphate shows potential interference with the PROmate® COVID-19 (q32) 2G Dry assay at therapeutic concentrations. Furthermore, these data show that the following substances show potential interference with the PROmate® COVID-19 (q32) 2G Dry assay at toxic concentrations: Whole Blood, 2,4-Dichlorobenyl Alcohol, Cetirizine Hydrochloride, and Zanamivir. All other substances tested do not significantly interfere with the assay.

Substances tested on anterior nasal swab samples in the direct to PCR workflow

Substance	Therapeutic Concentration (mg/ml)	Interference	Toxic Concentration (mg/ml)	Interference
Acetaminophen	0.030	None	0.2	None
Azelastine Hydrochloride	0.001	None	0.003	None
Beclomethasone	0.1	None	0.3	None
Benzocaine	0.2	None	0.6	None
Budesonide	0.128	None	0.384	None
Dexamethasone	0.0002	None	0.0006	None
Fluticasone propionate	0.0835	None	0.25	None
Guaifenesin	0.25	None	0.75	None
Mometasone furoate	0.0278	None	0.0835	None
Mucin	0.065	None	0.2	None
Mupirocin	0.5	None	1.5	None
Oxymetazoline	0.42	None	1.25	None
Phenylephrine	0.42	None	1.25	None
Red blood cells	10	None	30	Yes, reduction in positive and negative call rates to 86%
Sodium Chloride	6	None	9	None
Triamcinoline acetonide	0.0835	None	0.25	None

Substances tested on combined oropharyngeal/anterior nasal swab samples, extracted from VTM

Substance	Therapeutic Concentration (mg/ml)	Interference	Toxic Concentration (mg/ml)	Interference
2,4-Dichlorobenzyl Alcohol	0.023	None	0.069	Yes, reduction in positive call rate to 86%
Amylmetacresol	0.6	None	1.8	None
Cetirizine HCl	0.001	None	0.03	Yes, reduction in negative call rate to 83%
Oseltamivir phosphate	6	Yes, reduction in negative call rate to 14%	18	Yes, reduction in negative call rate to 86%
Tobramycin	0.004	None	0.024	None
Zanamivir	0.167	None	0.5	Yes, reduction in negative call rate to 86%

Due to the interference observed at the therapeutic concentration of Oseltamivir phosphate, a dose-response study was carried out.
*One or more samples were excluded from the call rate analysis as they produced inconclusive results by way of IEC failure.

Potential Interferent	Dose	Contrivance Status	Call Rate	% Call Rate	Interference
Oseltamivir Phosphate	100% Therapeutic	Negative	0/7	0%	No
	75% Therapeutic	Negative	0/6*	0%	No
	50% Therapeutic	Negative	1/7	14%	Yes
	25% Therapeutic	Negative	2/6*	33%	Yes
	0% Therapeutic	Negative	0/7	0%	No

10. Disposal

Dispose the unused kit reagents, human samples, and sealed post-amplification plates as clinical laboratory waste according to national regulations. Refer to Section 11 for guidance weblinks.
The PROmate® COVID-19 2G Sample Preparation Buffer contains Triton X-100 Reduced and is very toxic to aquatic life. Do not let product enter drains and any discharge into the environment must be avoided.

11. Facilities/Training Requirements

Testing for the presence of SARS-CoV-2 RNA should be performed in an appropriately equipped laboratory by staff trained to the relevant technical and safety procedures:

- UK Government guidance on handling and processing potential COVID-19 samples in laboratories: https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens
- World Health Organization Interim guidance on laboratory biosafety from 28 January 2021: Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases: https://www.who.int/publications/i/item/WHO-WPEGIH-2021.1
- Interim Guidelines for Collecting, Handling and Testing Clinical Samples from Persons under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

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Symbols	Meanings
	CE Mark
	EU Authorized Representative
	Batch Code
	*In Vitro* Diagnostics
	Keep away from sunlight (primer/probe mix)
	Catalogue number
	Consult Electronic Instructions for Use
	Manufacturer
	Positive Control
	Use by Date
	Single Use Symbol
	Storage temperature – Temperature Limit.
	Contains sufficient for n tests