GD-96
SARS-CoV-2 Kit

Frequently Asked Questions

Genedrive® 96 SARS-CoV-2 Kit

What is the Genedrive® 96 SARS-CoV-2 Kit?

Genedrive® 96 SARS-CoV-2 Kit is an *in vitro* diagnostic test for the rapid qualitative detection of the active SARS-CoV-2 infection. The test is performed using RNA extracts from upper respiratory tract specimens.

What is the intended use of the Genedrive® 96 SARS-CoV-2 Kit? (Full text in Kit IFU)

The Genedrive® 96 SARS-CoV-2 Kit is intended to be used for the qualitative detection of RNA from SARS-CoV-2 in upper respiratory specimens from individuals suspected of COVID-19 by their healthcare provider.

The Genedrive® 96 SARS-CoV-2 Kit is intended to be used by a laboratory professional proficient with molecular biology techniques.

What volume of sample is required for use with the Genedrive® 96 SARS-CoV-2 Kit?

Genedrive® 96 SARS-CoV-2 Kit requires 20 µL of swab-derived RNA extract to run the test.

What components are supplied with Genedrive® 96 SARS-CoV-2 Kit?

Each Genedrive® 96 SARS-CoV-2 Kit contains the following components:

- 1 X bar coded 96 well plate
- 1 x optical film seal
- 1 x desiccant pouch
- 1 x IFU

What is the product code for the Kit?

CE IVD products:
- ID-CoV2-01-LPC Low profile plate
- ID-CoV2-01-FPC Fast plate
- ID-CoV2-01-BPC Bio plate

US ONLY products:
- ID-CoV2-01-LPU Low profile plate
- ID-CoV2-01-FPU Fast plate
- ID-CoV2-01-BPU Bio plate

Please ensure you order the **correct plate type** for the correct Real-Time PCR instrument
(For full information refer to the kit IFU)

How many tests are in a Genedrive® 96 SARS-CoV-2 Kit?

The kit contains 1 x 96 well plate containing 96 reactions.

Where can I find a copy of the Genedrive® 96 SARS-CoV-2 Kit IFU?

This IFU can be obtained via the Genedrive website at www.genedrive.com or by scanning the QR code on the kit label.

What is the storage temperature of the Genedrive® 96 SARS-CoV-2 Kit?

The Genedrive® 96 SARS-CoV-2 Kit should be stored at 2-30 °C.

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Where can I find the expiry date for the Genedrive® 96 SARS-CoV-2 Kit?

The expiry date for the Genedrive® 96 SARS-CoV-2 Kit can be found on the kit label.

Who is the ideal customer for the Genedrive® 96 SARS-CoV-2 Kit?

Virology consultants, hospital/private laboratory managers.

Is the Genedrive® 96 SARS-CoV-2 Kit test performance affected by new variants of SARS-CoV-2?

The Genedrive® 96 SARS-CoV-2 test performance is not affected by new mutations and is still able to detect all published COVID-19 strains with the same high level of accuracy. This is because the test does not target the genes affected by the new mutations. The Genedrive® 96 SARS-CoV-2 test was specifically designed to target 2 separate genes, E (envelope protein) and N (nucleocapsid protein). New variants have involved mutations in the highly mutagenic S gene, which encodes the spike proteins.

The situation is continuously monitored and analysis is conducted to compare genetic sequences to ensure continued confidence.

How many tests can I perform in one day with the Genedrive® 96 SARS-CoV-2 Kit

Assuming a single Real-Time PCR system is in use, 4 runs could be conducted in a single 8 hour working day. Theoretically this enables the running of 384 samples if they have already been extracted (Extraction time is not included in assessment)

For a SARS-CoV-2 positive sample is it possible to differentiate whether the E or the N gene target was amplified?

As the probes for the E and the N gene targets have been designed to melt within the same temperature window it is not possible to differentiate which target amplified.

What should I do if the Genedrive® 96 SARS-CoV-2 Kit components are damaged?

Any components that show signs of damage should not be used, the test should be repeated using a new kit.

Is the Genedrive® 96 SARS-CoV-2 Kit CE-IVD marked?

Yes, the Genedrive® 96 SARS-CoV-2 Kit is CE-IVD marked.

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Specimen storage

What specimen type must be used with the Genedrive® 96 SARS-CoV-2 Kit?

Genedrive® 96 SARS-CoV-2 Kit is designed for use with RNA extracts derived from upper respiratory tract swabs.

Can frozen specimens be used with the Genedrive® 96 SARS-CoV-2 Kit

Yes, frozen specimens can be used, assuming that the specimen has not undergone more than one freeze/thaw cycle. The sample should be thawed on ice prior to use.

Can I use specimens straight from the fridge?

Yes, samples can be used straight from the fridge and do not need to be at room temperature prior to processing.

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What additional materials are required to run a Genedrive® 96 SARS-CoV-2 Kit?

Reagents:
- RNA extraction kit
- Positive control
- Negative control
- Molecular grade nuclease free water (e.g. Sigma W4502)
- Human Lymphocyte RNA (AMSBIO, ATR1254148-10)) (Extraction control) This accessory can be obtained from Genedrive

Equipment:
- RNA extraction instrument (optional)
- Real-Time PCR instrument
- Powder free disposable gloves
- Calibrated pipettes (P20)
- Plate centrifuge
- Class 2 safety cabinet
- Vortex with 96 well plate or flat attachment
- Single-use RNase, DNase-free aerosol resistant pipette tips (p20)
- Any PPE required by local safety guidelines
- 96 well cool block
- Genedrive® 96 Exporter software (GE-01)

Can I use the Genedrive® 96 SARS-CoV-2 Kit straight from the fridge?

Yes, the kit does not need to be warmed up to room temperature prior to use.

How long does it take to perform a Genedrive® 96 SARS-CoV-2 test?

Result is available in between 100-119 minutes from run initiation (platform dependent)

Can I use a vortex to mix reactions once the sample has been added?

Yes, mixing by vortex of the sample is critical for thorough mixing of reactions within the sealed plate.

Once opened, how long are the Genedrive® 96 SARS-CoV-2 Kit components stable for?

The sealed plate is stable for 5 days after removal from the foil pouch. Once the seal is opened the plate is stable for up to 4 hours.

My RNA extraction method is not listed as a validated method, am I still able to use this method?

If your preferred RNA extraction method is not listed as a validated method for use with the Genedrive® 96 SARS-CoV-2 Kit we recommend performing validation by testing known high, medium, low viral load and negative specimens extracted using your method. Some methods may have more carryover of PCR inhibitors, especially automated methods. We recommend setting automated RNA extraction methods to input specimen volume of 200 µL and an eluate volume of 40 µL to reduce carryover of inhibitory substances. Inhibition from carryover of inhibitory substance may also be reduced by reducing the volume of extracted specimen added to each well to 10 µL and adjusting the volume to 20 µL using molecular grade nuclease free water.

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Can I use the test if I don't have a vortex mixer?

Yes, if you cannot use a vortex mixer (for example if you have an automated laboratory platform), you may perform pipette mixing. See the IFU for further details.

Why does the Genedrive® 96 SARS-CoV-2 Kit require the use of a cool block?

After the addition of the sample the freeze dried assay begins to reconstitute. Keeping the reagents cool lowers the activity of the enzymes within the mix. This in turn minimises the potential of spurious PCR products being generated by the enzymes.

Can I automate sample pipetting into the Genedrive® 96 SARS-CoV-2 Kit?

Genedrive have not validated any automated pipetting methods, however the plates are compatible with any instrument that has been trained to use low profile, bio plates or fast plates. An end user validation will be required before using this workflow.

What is carrier RNA and why is it needed for RNA extraction?

The use of carrier RNA increases the yield of RNA that is extracted from analytical specimens especially when specimens contain a low concentration of RNA.

How does melt curve analysis work?

Specific probes are designed to melt from their target DNA sequences during discrete temperature ranges.

The fluorophore attached to the probes emits fluorescence when bound and is dark when not bound.

Melt curve functions by slowly increasing the temperature of the reaction and measuring for fluorescence. When probes melt from their target the fluorescence decreases and is detected by the instrument.

The Genedrive® 96 SARS-CoV-2 Kit only uses one fluorophore (FAM) but there are 3 targets. How can you differentiate between which targets have amplified?

The Genedrive® 96 SARS-CoV-2 Kit functions using melt curve analysis not real-time PCR. This means the instrument looks for decrease of fluorescence within different melt temperature (Tm) ranges. As each target is designed to be observed within a different Tm it is possible to use the same fluorophore for all probes.

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Quality Control

Does the Genedrive® 96 SARS-CoV-2 Kit contain an internal control?

Yes, the Genedrive® 96 SARS-CoV-2 Kit contains an internal PCR control (IPC). Presence of a peak for this target indicates that PCR occurred as expected and inhibitors were not present.

Does the Genedrive® 96 SARS-CoV-2 Kit contain an extraction control?

The Genedrive® 96 SARS-CoV-2 Kit targets and amplifies endogenous human RNase P, intended to ensure that human sample is present in the amplification reaction. However, levels of endogenous human RNA present may be donor or extraction kit dependent. Users have the option to 'spike' the patient specimen with the recommended human RNA control material to normalise RNase P levels prior to the RNA extraction process.

Which Universal Human Reference RNA would you recommend?

AMSBIO Human Lymphocyte RNA (Part number: ATR1254148) has been validated for use with the Genedrive® 96 SARS-CoV-2 Kit. Refer to the Kit IFU for detailed instructions for the volume of RNA to add to the extraction kit buffer. This accessory can be obtained from Genedrive.

What quality control schedule should I follow for the Genedrive® 96 SARS-CoV-2 Kit?

This is dependent upon local procedures and set individually by each customer.

What run control material is available for use with the Genedrive® 96 SARS-CoV-2 Kit?

The Genedrive® 96 SARS-CoV-2 Kit has been validated using the following run controls:

Positive:
- Exact Diagnostics SARS-CoV-2 standard
- IDT 2019-nCOV_N Positive control
- Accuplex SARS-COV-2 Reference material kit (positive control)
- Accuplex SARS-COV-2 verification panel

Negative:
- Nuclease free water

For further information review the Quality Control section of the Genedrive® 96 SARS-CoV-2 Kit IFU.

What does an IPC fail result mean?

An IPC fail means that neither the target or internal control sequences have been detected in the specimen.

This can be caused by the following:

- A poor quality specimen
- Contamination with PCR inhibitor
- Incorrect running of the test

Repeat the test using a new kit, taking care to follow all the steps as outlined in the IFU.

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What should I do if a known negative control specimen tests positive with the Genedrive® 96 SARS-CoV-2 Kit?

If a know negative results in a positive result then there may be local contamination present. Clean the area thoroughly. Wipe down all equipment and surfaces. To avoid contamination follow procedures applicable for good PCR practice. Do not open the 96 well plates once the test is complete. Dispose of the plates immediately after use as clinical waste. For further support contact your local distributor.

What could cause a false negative result?

- A positive sample below the LoD
- Poor specimen quality
- Poor specimen extraction
- Poor PCR set-up
- Not following the IFU

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Real-Time PCR instrument information

What platforms can I use the Genedrive® 96 SARS-CoV-2 Kit on?

The Genedrive® 96 SARS-CoV-2 Kit has been validated on the following Real-Time PCR instruments:

- Roche LightCycler 480 II
- Bio-Rad CFX96 Real-Time PCR Detection System
- ABI 7500 Fast Real-time PCR instrument

Why can't I use the Genedrive® 96 SARS-CoV-2 Kit on any other Real-Time PCR instruments?

The kit has been designed to prioritise ease of use. The chemistry is provided lyophilised, as beads, in the end-use plate for the instruments listed within the IFU. This means an operator simply has to transfer an extracted sample to a well and does not have to prepare chemistry in advance.

The plates may fit other instruments however this has not been validated by Genedrive Diagnostics Ltd. and therefore will require validation by the end user before use.

The correct plate format is required for the correct Real-Time PCR instrument.

Do I have to set up the PCR run manually each time on my Real-Time PCR instrument?

No, for ease and speed of set-up PCR run templates for all validated instruments are available from the Genedrive website at:

https://genedrive.com/assays/sars-cov-2-kit-assay.php

The Kit IFU states that SYBR green settings must be used on the detection instrument. SYBR green is an RUO reagent how can it be included in the chemistry for the Genedrive® 96 SARS-CoV-2 Kit?

The Genedrive® 96 SARS-CoV-2 Kit does not contain SYBR green chemistry. The kit functions using fluorescently labelled probes. The settings in the instrument are required to use certain parameters.

If the power is cut from the instrument during a run will I still get a result?

If the instrument loses power during a run then it will not be possible to gain a result and a test should be repeated, if time allows. This can be mitigated by connecting the instrument to an uninterrupted power supply unit.

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Result interpretation

Can I perform the result interpretation automatically?

Yes, Genedrive have developed the Genedrive® 96 Exporter software, a software solution for automatic and fast result interpretation. The application may be downloaded from the Genedrive website at http://genedrive.com/assays/genedrive-96-exporter.php

Simply follow the steps in the Kit IFU for use of the software.

How do I use the RNase P extraction control with the Genedrive® 96 Exporter software?

When interpreting results from a run where an RNase P extraction control has been added, ensure the 'Extraction Control Used' check box is checked in the Genedrive® 96 Exporter software. Conversely – if you have not added an RNase P extraction control, ensure the 'Extraction Control Used' check box is unchecked.

I'm performing a manual interpretation of a 'Check Result' flag using the Genedrive® 96 Exporter software, but I'm not sure what the result is, what should I do?

Manual interpretation of borderline specimens can be made easier by selecting the wells containing the positive and negative run controls, alongside the specimen well you are trying to interpret.

To do this hold the 'Ctrl' key on your keyboard and select the wells. First compare the IPC peaks for the run controls against the specimen well. Next compare the CoV-2 peaks. What may look like a peak when the well of interest is 'zoomed in' can sometimes be noise in the baseline, which is apparent when having a true peak to compare it with.

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Genedrive® 96 SARS-CoV-2 Kit Performance

What is the diagnostic sensitivity and specificity of the Genedrive® 96 SARS-CoV-2 Kit?

The sensitivity is 100% and the specificity is 99.2% based on the CE IVD validation.

What is the diagnostic accuracy of the Genedrive® 96 SARS-CoV-2 Kit when using clinical specimens?

For US ONLY IFU Data:

Positive percent agreement (PPA) was 100% (96.30% – 100.00%, 95% CI)

Negative percent agreement (NPA) was 100% (92.87% – 100.00%, 95% CI)

What is the Limit of Detection (LoD) of the Genedrive® 96 SARS-CoV-2 Kit?

The LoD is 0.5 copies/µL, or 10 copies/reaction.

What is *in silico* analysis?

In silico is an expression meaning performed on a computer. For analytical exclusivity the Genedrive® 96 SARS-CoV-2 Kit primers and probes have been tested using bioinformatics methodology to show low homology to the respiratory pathogens listed in the IFU.

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Health and Safety

What safety precautions should I follow when using the Genedrive® 96 SARS-CoV-2 Kit?

Specimens must be labelled and handled with care according to local health and safety regulations. Gloves must be worn at all times when handling the assay. To avoid contamination all materials must be disposed of immediately after usage (labelled RNA extracts may be stored according to local procedures) in order to prevent false positive results follow applicable procedures for good PCR practice.

What good PCR practice should I follow when using the Genedrive® 96 SARS-CoV-2 Kit?

Always wear gloves when handling the assay. Prevent cross contamination of specimens. Ensure proper storage and handling of the reagents. Ensure all specimens are appropriately labelled. Dispose of 96 well plates into clinical waste after usage. Do not open any 96 well plates after the PCR amplification has been conducted.

Can the Genedrive® 96 SARS-CoV-2 Kit be reused?

No, each Genedrive® 96 SARS-CoV-2 96 well plate can only be used once.

Do I need to use any special procedures to dispose of the plates once the test has been completed?

No, the Genedrive® 96 SARS-CoV-2 Kit does not produce any waste that requires special disposal procedures, therefore reducing the burden on running costs and reducing the environmental impact of the assay. Follow your local health and safety guidelines for clinical waste disposal.

Once the test is completed can I open the Genedrive® 96 SARS-CoV-2 96 well plate?

No, once the test is complete DO NOT attempt to remove the seal, as this could result in environmental contamination with PCR amplicons. Upon completion of the test the plate should be removed and discarded as clinical waste.