PACKAGE INSERT AND COLOUR CHART
SARS-COV-2 DIAGNOSTIC KIT (FOR RESEARCH USE ONLY)

KIT CONTENTS

1. Test Cartridges, Qty. 25 (Note: Quantity may vary as per the customer's order)
2. Package Insert (PI)
3. Instructions for use (IFU)
4. Safety Data Sheet (SDS)
5. Certificate of Analysis (CoA)

SUMMARY AND EXPLANATION

Covid-19 is a disease caused by severe acute respiratory syndrome coronavirus 2. SARS-CoV-2 is a single- stranded, positive-sense RNA virus capable of person-to-person transmission and can cause mild to severe respiratory illness including death. QuikPath SARS-CoV-2 diagnostic test kit is an IVD test utilizing isothermal PCR and colorimetric dye-based sensing for the qualitative and visual detection of the covid-19 SARS-CoV-2 viral RNA. In this package insert, we have provided pertinent and timely information about the QuikPath SARS-CoV-2 diagnostic test kit.

TEST DESCRIPTION

QuikPath SARS-CoV-2 Diagnostic Test Kit is a Nucleic Acid Amplification Test for detection of SARS-CoV-2 RNA. It uses Reverse transcriptase Loop-mediated isothermal amplification in a sample-to-result cartridge format, wherein presence of virus results in colour change in the tube from pink to yellow after 40 minutes incubation. The test gives a qualitative positive or negative result based on colorimetric readout which is detected by eye. Test is performed by inserting nasopharyngeal or oropharyngeal swab specimens into buffer chamber in Cartridge to solubilize the sample. The pistons of the Cartridge are pulled up to maximum height and plunged down to the bottom. This transfers an aliquot of buffer into the reaction chamber of cartridge which amplifies any existing viral RNA. Cartridge contains buffer, enzymes, and colorimetric reagents, required for four assay steps: Lysis of the virus, Reverse transcription of viral RNA to cDNA, Nucleic acid amplification, and Detection. To run the reaction, heat block set at 65 °C for 40 minutes and test result is interpreted by visualizing colour change in the tubes of the Test Cartridge.

INDICATION

QuikPath SARS-CoV-2 Diagnostic Test Kit uses nasopharyngeal and oropharyngeal swab specimens, collected from patients suspected of covid-19 by healthcare provider. **Positive results** are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. SARS-CoV-2 RNA is generally detectable in nasopharyngeal or oropharyngeal swab specimens during acute phase of infection. Positive results do not rule out bacterial infection or co-infection with other viruses. **Negative results** do not preclude SARS-CoV-2 infection and should not be used as sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Testing with the QuikPath SARS-CoV-2 Diagnostic Test Kit is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.

WARNINGS AND PRECAUTIONS

- Do not use if pouch contents are damaged; Do not use Test kit after expiration.
- Single- use only; Do not re-use the Test Cartridges and reagents.
- Store at -25 °C to -15 °C.
- For optimal performance, use the Specimen Collection Swabs recommended by CDC.
- For detailed instructions, refer the enclosed IFU.
- Positive and negative control swabs to be purchased separately.

Disclaimer: This kit has received Provisional Authorisation from the Health Sciences Authority in Singapore. This Test Kit may solely be used for research use or evaluation purpose and not for clinical purposes and may not be resold or used for any other purpose. Any intentional or unintentional use will not hold QuikPath Pte. Ltd. liable.

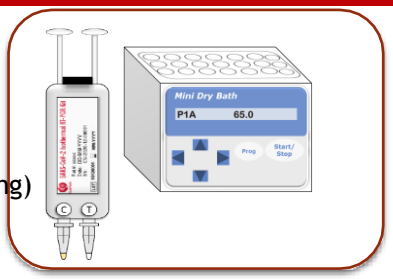
SARS-COV-2 ISOTHERMAL RT- PCR KIT (FOR RESEARCH USE ONLY)

Note: The product images are for illustration purposes only and may not be the exact representation of the product

STEPS TO PERFORM THE TEST

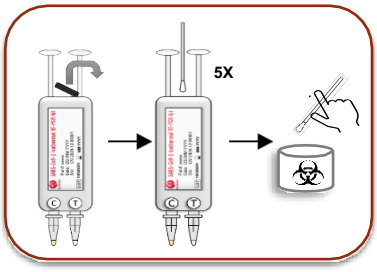
1. INITIAL SET-UP

- Remove Test Cartridge from the pouch.
- Let it equilibrate at room temperature for 5 minutes.
- Unpack the heat block, connect power cord to the back of the unit, then plug into a grounded outlet; turn the switch on.
- Press Start button. (Note: The programme is set to default **P1A**, do not change this setting)
- Wait for the temperature to reach 65°C.
- Meanwhile, record the Patient ID and Test date on the Cartridge label.



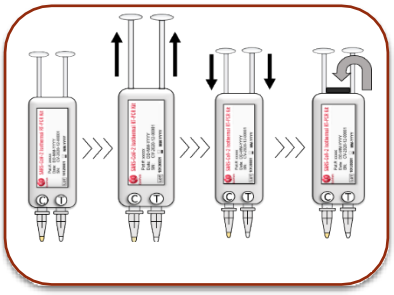
2 . SWABBING AND CARTRIDGE INSERTION

- Remove Test Cartridge lid and set aside. Insert the Specimen swab into the buffer chamber until it touches the bottom of the chamber.
- Rotate the swab 5x in the chamber to dislodge the sample into the buffer.
- Remove Specimen swab from the buffer chamber and discard into biohazardous waste container.



3. REACTION ACTIVATION

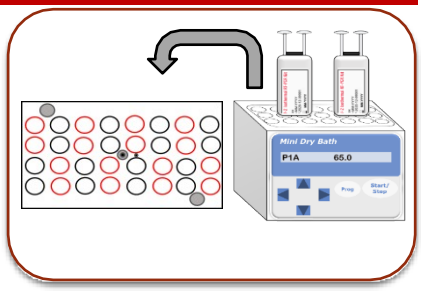
- From the initial position (Fig-a), pull both pistons upwards ~2cm (Fig-b), then immediately push down completely till the pistons do not move downwards any further (Fig-c). Volume of liquid in two tubes will increase if done correctly. Close the Cartridge lid, make sure it is secure (Fig-d).
- Record colour of liquid in two tubes (C & T) by comparing to **Colour Chart** below. This is called the **"Initial colour grade"**
  - *If the colour grade is 3 to 5, proceed with the test.*
  - *If colour grade is 1 or 2, test is invalid; re-start the test using a new cartridge.*



4. RUN THE TEST

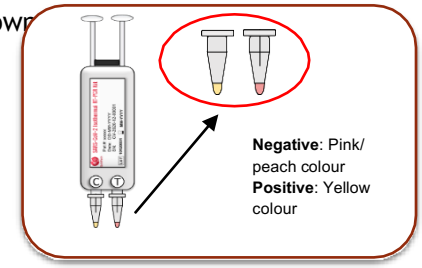
- Insert the Test Cartridge into the heat block for 40 minutes, in the red marked holes only, as shown in Fig- 4(a).
- Push the Test Cartridge downwards to ensure tight fit (Fig-4(b)).
- Ensure both the tubes of the Cartridge are inserted into the heat block properly.

Note: Do not move the Test Cartridge and the heat block until the test is completed.



5. VISUALIZE THE RESULT

- After 40 minutes, remove the Test Cartridge from heat block. Let the Cartridge cool down 5 minutes to room temperature. Observe colour of the reaction in the two tubes (C & T).
- Record the colour of liquid in two tubes (C & T) again by comparing to the **Colour Chart** below. This is called the **"Final colour grade".**
- Please refer to the tubes images in the **Results Interpretation table** below.



INTERPRETATION OF TEST RESULT

Note: Look closely at the colour change in both tubes (C and T) to interpret the test results. Visualize the tubes in natural lighting. Individuals with colour-impaired vision may not be able to adequately interpret test results.

1) Refer to the **Colour Chart** below for steps to determine Positive and Negative Results. Also refer to the images in the **Results Interpretation table** below for test results validity interpretation.

Colour Chart

GRADE 1	GRADE 2	GRADE 3	GRADE 4	GRADE 5
				

2) In **Colour Chart**, find difference between Initial colour grade (Test procedure-step 3) & final colour grade (Test procedure-step 5)

3) If, **(Final colour grade — Initial colour grade) >= 2: Test result is Positive**

If, **(Final colour grade — Initial colour grade) < 2: Test result is Negative**

Results Interpretation table

Note: In the below table, "+" symbol denotes positive, "-" symbol denotes negative.

Tubes Colour after Reaction	Internal Control Tube (C)	Test Sample Tube (T)	Interpretation
	+	+	Test result is valid. SARS-CoV-2 is detected
	+	-	Test result is valid. SARS-CoV-2 is not detected
	-	+	Test result is invalid. Sample should be re-tested
	-	-	Test result is invalid. Sample should be re-tested

Note: If an invalid result is obtained, the sample may be rerun. A new sample should be collected and run with a new Test Cartridge.