COVID-19 Rapid Antigen Test (Saliva)

Catalogue Number: RAPG-CVA-119

Please read this manual carefully before operating to ensure proper use.

TEST KIT DESCRIPTION AND INTENDED USE

The Biopanda COVID-19 Saliva Antigen Rapid Test is a qualitative lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antigens in saliva specimens.

It is intended for use as a tool to assist in the diagnosis of SARS-CoV-2 infections, in conjunction with other tests.

This test is for *in vitro* diagnostic use only by a trained healthcare professional.

TEST PRINCIPLE

The Biopanda COVID-19 Saliva Antigen Rapid Test is a qualitative lateral flow immunoassay for the detection of SARS-CoV-2 antigens in human saliva specimens.

The test cassette contains recombinant SARS-CoV-2 antibody conjugated to coloured particles. When a specimen is added to the sample well of the cassette, any SARS-CoV-2 antigens present in the specimen will bind to the antibody conjugate, forming coloured coronavirus antigen-antibody complexes. This mixture migrates laterally along the membrane to the test region. In this test region, SARS-CoV-2 antibodies have been immobilised onto the membrane. These capture any coloured complexes that have formed, resulting in the appearance of coloured lines.

Therefore, if the specimen contains SARS-CoV-2 antigens, a coloured line will appear in the test line region. A coloured line should always appear in the control line region, indicating that the proper volume of specimen has been added to allow the assay to run. Note that the presence of the control line does not guarantee the quality of the saliva specimen that was collected.

KIT CONTENTS

- 10 x foil wrapped test cassettes
- 10 x plastic waste bags
- 10 x saliva collection funnels
- 10 x extraction tubes with dropper tips
- 10 x extraction buffer ampoules
- 10 x pipettes
- 1 x workstation
- 1 x instructions for use

EQUIPMENT REQUIRED BUT NOT SUPPLIED

- Timer

STORAGE AND HANDLING

Store the kit at between 2-30°C in a cool, dry place away from direct sunlight. **DO NOT FREEZE**. Refrigeration is not necessary. The test cassettes are stable up until the expiry date printed on the foil pouch as long as the pouch has not been opened.

Do not open the foil pouch until you are ready to run the test. Do not touch the sample well or results window of the cassette.

PRECAUTIONS

- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- All samples should be considered as potentially infectious and handled accordingly. Disposable gloves and a laboratory coat should be worn.
- Ensure the test kit is at room temperature (RT 15-30°C) before running the test. Extremes of humidity and temperature can adversely affect results.
- Keep the test inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- Tests that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test.
- Used tests, collection funnels, extraction tubes, buffer ampoules and pipettes should be sealed in supplied plastic waste bags and disposed of in a safe manner according to local regulations.

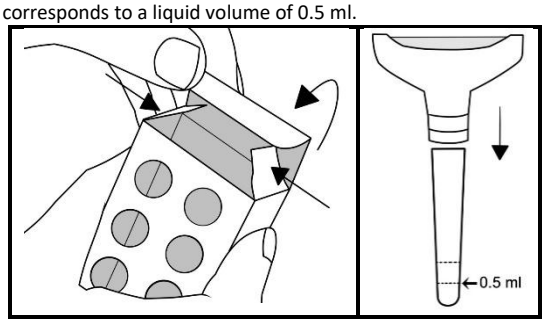
SPECIMEN COLLECTION

- Before collecting saliva, instruct the patient not to place anything in their mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.
- Instruct the patient to deeply cough 3-5 times to move sputum from deep in the throat up to the mouth.
- It is recommended to collect the first saliva specimen after deeply coughing in the morning, but saliva collected at any time of the day may be used.
- The saliva specimen should be collected using the items provided with the kit. Follow the detailed Test Procedure below. No other collection device should be used with this assay.
- Specimens should be tested as soon as possible after collection. If saliva is not to be processed immediately, it is stable for up to 2 hours at room temperature and 24 hours at 2-8°C.

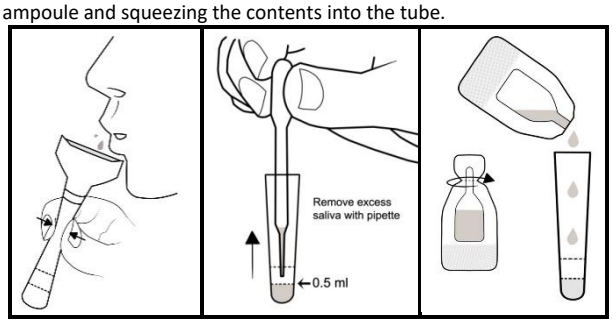
TEST PROCEDURE

Allow the test cassette, specimen and extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

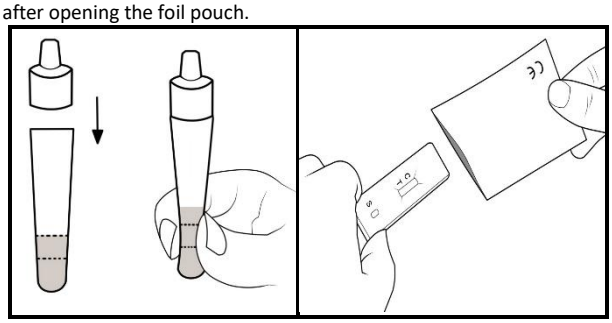
1. Assemble the cardboard workstation so that it is ready for use.
2. Take a saliva collection funnel and attach it to an extraction tube. Each extraction tube is marked with two lines; the bottom line corresponds to a liquid volume of 0.5 ml.



3. While gently squeezing the extraction tube, collect 0.5 ml of saliva from the patient. If too much saliva was collected, remove excess saliva using a pipette provided so that 0.5 ml remains in the tube.
4. Remove the collection funnel, then carefully add the contents of one extraction buffer ampoule by twisting off the top of the plastic ampoule and squeezing the contents into the tube.



5. Fit a dropper tip onto the tube, then repeatedly but gently squeeze the bottom of the tube to mix the saliva and buffer for 10 seconds. Place the tube upright into the assembled workstation.
6. Remove the test cassette from the sealed foil pouch and place it on a clean, level surface. The cassette should be used within one hour but best results will be obtained if the test is performed immediately after opening the foil pouch.



7. Invert the extraction tube and add 3 **drops of the extracted specimen** to the specimen well (S) and then start the timer.

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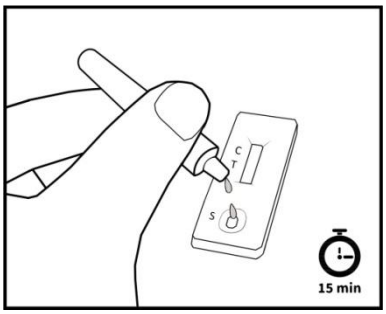


8. Wait for the coloured line(s) to appear. Read the result at **15 minutes**. Do not interpret the result after 20 minutes as a false-positive line may eventually appear over time.

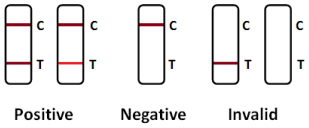
INTERPRETATION OF RESULTS

POSITIVE: Two distinct coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the test line region (T).

Note: The intensity of the line in the test line region will vary based on the amount of SARS-CoV-2 antigens present in the sample. So any shade of colour in the test region should be considered a positive result.

NEGATIVE: One coloured line appears in the control region (C). No apparent coloured line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. If the test is working properly, the strip background in the results area should be white to light pink and not interfere with the ability to read the test result.

It is also recommended to test with external positive and negative quality controls to ensure the correct test procedure is being followed and to verify the test performance.

LIMITATIONS OF THE TEST PROCEDURE

1. The Biopanda COVID-19 Saliva Antigen Rapid Test is for *in vitro* diagnostic use only, for the detection of SARS-CoV-2 antigen in human saliva specimens.
2. This test will only indicate the presence of SARS-CoV-2 antigen in the specimen. Neither the quantitative value nor the rate of change of the concentration of SARS-CoV-2 antigen can be determined by this qualitative test.
3. A negative result does not rule out the possibility of infection. The viral load in the patient may be too low at time of testing or a poor quality saliva specimen was obtained.
4. A definitive diagnosis should not be based on results from this test alone. The results must be considered with other clinical information such as the patient's exposure history, symptoms or lack thereof, and other test results available to the physician.
5. If the test result is negative and clinical symptoms persist, it is recommended to re-test the patient a few days later or to test with a molecular diagnostic test to rule out infection in these individuals.
6. This test does not provide any information about the infectiousness of an individual.

PERFORMANCE CHARACTERISTICS

CLINICAL SENSITIVITY AND SPECIFICITY

The Biopanda COVID-19 Rapid Antigen Test (Saliva) has been evaluated with saliva specimens obtained from symptomatic and asymptomatic patients. RT-PCR was used as the reference test method.

		RT-PCR		Total
		Positive	Negative	
COVID-19 Saliva Rapid Antigen Test	Positive	99	2	101
	Negative	6	309	315
Total		110	311	416

Positive percent agreement (sensitivity): 94.3% (95%CI: 88.0% – 97.9%)
Negative percent agreement (specificity): 99.4% (95%CI: 97.7% – 99.9%)
Overall agreement: 98.1% (95%CI: 96.3% – 99.2%)

ANALYTICAL SENSITIVITY (LIMIT OF DETECTION)

The Biopanda COVID-19 Saliva Antigen Rapid Test was tested using recombinant SARS-CoV-2 antigen and heat-inactivated cultured SARS-CoV-2 virus spiked into negative saliva specimens. The limit of detection is 50 pg/ml SARS-CoV-2 antigen, and $4 \times 10^{1.53}$ $TCID_{50}$/ml viral titre.

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

The Biopanda COVID-19 Rapid Antigen Test was tested with the following viral and bacterial confounder specimens. No discernible line at the test-line region was observed at the concentrations listed.

Description	Concentration	Description	Concentration
Recombinant MERS-CoV Nucleocapsid protein	50 µg/ml	HCoV 229E	1.0×10^6 PFU/ml
H1N1 Influenza A	1.0×10^6 PFU/ml	HCoV OC43	1.0×10^6 PFU/ml
H1N1pdm09 Influenza A	1.0×10^6 PFU/ml	HCoV NL63	1.0×10^6 PFU/ml
H3N2 Influenza A	1.0×10^6 PFU/ml	HCoV HKU1	1.0×10^6 PFU/ml
Influenza B (Yamagata)	1.0×10^6 PFU/ml	*Legionella pneumophila*	1.0×10^7 CFU/ml
Influenza B (Victoria)	1.0×10^6 PFU/ml	*Chlamydia pneumoniae*	1.0×10^7 CFU/ml
Adenovirus (types 1, 2, 3, 5, 7, 55)	1.0×10^6 PFU/ml	*Mycoplasma pneumoniae*	1.0×10^7 CFU/ml
RSV	1.0×10^6 PFU/ml	*Streptococcus pyrogenes*	1.0×10^7 CFU/ml
Human metapneumovirus	1.0×10^6 PFU/ml	*Haemophilus influenza*	1.0×10^7 CFU/ml
Parainfluenza virus (types 1, 2, 3, 4)	1.0×10^6 PFU/ml	*Streptococcus pneumoniae*	1.0×10^7 CFU/ml
Enterovirus	1.0×10^6 PFU/ml	*Candida albicans*	1.0×10^7 CFU/ml
Rhinovirus	1.0×10^6 PFU/ml	*Staphylococcus aureus*	1.0×10^7 CFU/ml

INTERFERING SUBSTANCES TESTING

The Biopanda COVID-19 Rapid Antigen Test was tested with the following potentially interfering substances, and was found not to be affected at the tested concentrations.

Description	Concentration	Description	Concentration
Benzocaine	5 mg/ml	Oxymetazoline	15 %
Dexamethasone	5 mg/ml	Phenylephrine	15 %
Fluticasone propionate	5 %	Ribavirin	5 mg/ml
Histamine dihydrochloride	10 mg/ml	Saline nasal spray	15 %
Menthol	10 mg/ml	Tobramycin	5 µg/ml
Mucin	2%	Triamcinolone	10 mg/ml
Mupirocin	10 mg/ml	Whole Blood	4%
Oseltamivir phosphate	10 mg/ml	Zanamivir	5 mg/ml

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test	IVD	*in vitro* diagnostic medical device
	Consult instructions for use	LOT	Batch code
	Storage temperature	Σ	Contains sufficient for <*n*> tests
REF	Catalogue number		

Thank you for purchasing Biopanda's COVID-19 Rapid Antigen Test kit. Please read this manual carefully before operating to ensure proper use.

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