COVID Ag FIA Rapid Test Device

(Nasopharyngeal Swab)

FI2-CVA-001

This test is for use with the Biopanda Fluorescence Immunoassay Analyser only. Please read this manual carefully before operating to ensure proper use.

TEST KIT DESCRIPTION AND INTENDED USE

The Biopanda COVID-19 Antigen FIA Rapid Test is a qualitative lateral flow fluorescence immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab 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 Antigen FIA Rapid Test is a qualitative membrane-based fluorescence immunoassay for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens. The test cassette contains recombinant SARS-CoV-2 antibody conjugated to fluorescent microspheres. 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 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 complexes that form. The fluorescence immunoassay analyser then detects the fluorescent signal value in the test region and determines the result of the test.

KIT COMPONENTS

- 25 x foil wrapped test cassettes
- 25 x plastic extraction tubes and tips
- 1 x extraction buffer bottle
- 25 x sterile swabs
- 1 x Workstation
- 1 x ID card (COVID-19 Antigen)
- 1 x instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Biopanda Fluorescence Immunoassay Analyser

STORAGE AND HANDLING

Store the kit at between 4-30°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.

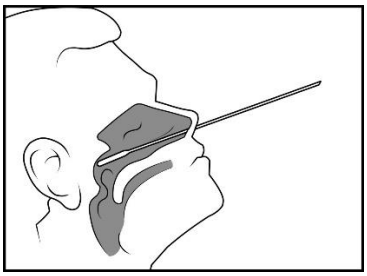
Do not open the foil pouch until you are ready to run the test. Do not touch the sample well or results window of the cassette.

PRECAUTIONS

1. This kit is for professional *in vitro* diagnostic use only by trained health professionals.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. To obtain accurate results, do not use visually bloody or overly viscous samples.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. The Biopanda COVID-19 Antigen FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Analyser.

SPECIMEN COLLECTION

- Carefully insert the sterile swab into the nostril, parallel to the palate (and not upwards) until resistance is encountered where it has reached the surface of the nasopharynx.
- Gently rub and roll the swab head over against the nasopharynx. Leave the swab in place for several seconds, then slowly withdraw the swab while rotating it.
- If the head of the swab has not been saturated with fluid from the first collection, it can be re-inserted into the other nostril to collect specimens from the other side.



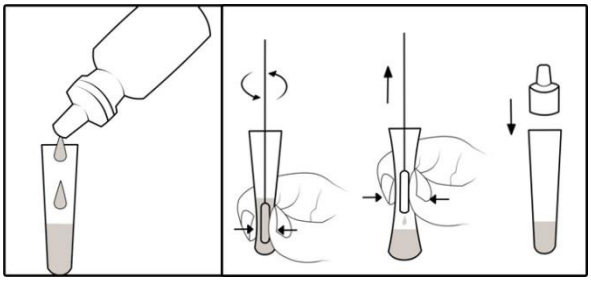
SPECIMEN TRANSPORT AND STORAGE

Freshly collected swab specimens should be tested as soon as possible after collection. If it is not possible to process immediately, the swab should be placed into a dry, sterile, tightly sealed plastic tube for storage. The specimen may be stored at 2 - 8°C for up to 24 hours, and for long-term storage, frozen at -70°C. The specimen should not be subjected to repeated freeze-thaw cycles.

SPECIMEN PREPARATION

Only use the extraction buffer and tubes supplied with this kit to process the swab specimens. Do not use specimens that have been placed into VTM or other transport media designed for use in molecular diagnostic tests.

1. Place the required number of extraction tubes into the workstation. Add 10 drops of buffer (approx. 350 µl) to each tube.
2. Place the swab specimen into an extraction tube with buffer. Immerse the swab head in the buffer by gently squeezing the bottom of the tube. Rotate the swab several times while squeezing it through the tube for 10 seconds.
3. Remove the swab while squeezing the sides of the tube against the swab head to extract as much liquid as possible from the swab.
4. Fit a dropper tip to the top of the extraction tube. The extracted specimen should be tested as soon as possible. The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.



TEST PROCEDURE

There are two test modes for the Biopanda Fluorescence Immunoassay Analyser: Standard Test mode and Quick Test mode.

“Quick test” mode: Insert the test cassette into the Analyser at 10 minutes after sample application and press "New Test", the Analyser will read and provide the test result after a few seconds.

“Standard test” mode: Insert the test cassette into the Analyser immediately after sample application and press "New test" at the same time. The Analyser will automatically count down the 10 minute before reading the test. Refer to the Biopanda Fluorescence Immunoassay Analyser Operation Manual for the complete instructions on use of the analyser. The test should be conducted at room temperature.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to your user requirements, select either “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyser port.
3. Remove the test cassette from the sealed foil pouch and use it within one hour. Best result will be obtained if the test is performed immediately after opening the foil pouch.
4. Invert the specimen collection tube and add 3 drops of the extracted specimen (approx. 100 µl) to the specimen well (S) of the cassette and then start the timer if using the “Quick test” mode. If using “Standard test” mode, insert the cassette into the Analyser and select the “New test” option.

INTERPRETATION OF RESULTS

The test results are calculated by the Biopanda Fluorescence Immunoassay Analyser and displayed on the screen. For additional information, please refer to the user manual of the Biopanda Fluorescence Immunoassay Analyser.

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with an accompanying value. This value is calculated by dividing the test signal of the sample by the cut-off value (S/C Ratio).

- Test results of Value ≥ 1.00 are considered positive for SARS-CoV-2 Antigen.

- Test results of Value < 1.00 are considered negative for SARS-CoV- 2 Antigen.

QUALITY CONTROL

Each Biopanda COVID-19 FIA Rapid Test contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by the Analyser. An invalid result from the internal control causes an error message on the Analyser indicating that the test should be repeated. An invalid result from the internal control causes an “N/A” message on the Biopanda Fluorescence Immunoassay Analyser. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control 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. Positive/Negative Controls are not included in this kit. However, it is recommended to test with external controls to ensure the correct test procedure is being followed and to verify the test performance.

LIMITATIONS OF THE TEST

1. The Biopanda COVID-19 Antigen FIA test is for *in vitro* diagnostic use only, for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens.
2. This test will only indicate the presence of SARS-CoV-2 antigen in the specimen. Although the Analyser provides a numerical result readout, neither the quantitative value nor the rate of change of the concentration of SARS-CoV-2 antigen should be determined using 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 swab 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.
7. The performance of the Biopanda COVID-19 Antigen FIA test was evaluated using the procedures provided in this package insert only. Deviation from these procedures may alter the performance of the test.

PERFORMANCE CHARACTERISTICS

CLINICAL SENSITIVITY AND SPECIFICITY

The Biopanda COVID-19 Antigen FIA Rapid Test has been evaluated with specimens obtained from the patients. RT-PCR was used as the reference test method.

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen FIA Rapid Test	Positive	43	1	44
	Negative	2	60	62
Total		45	61	106

Positive percent agreement (sensitivity): 95.6% (95%CI: 84.9% – 99.5%)
Negative percent agreement (specificity): 98.4% (95%CI: 91.2% – 99.9%)
Overall agreement: 97.2% (95%CI: 92.0% – 99.4%)

ANALYTICAL SPECIFICITY (CROSS-REACTIVITY)

No cross-reactivity or interference was observed with the following microorganisms when tested at these concentrations presented in the table below.

Description	Concentration	Description	Concentration
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/ml	Arcanobacterium	1.0x10^8 org/ml
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/ml	Candida albicans	1.0x10^8 org/ml
Human coronavirus OC43	2.45 x 10^6 LD_{50}/ml	Corynebacterium	1.0x10^8 org/ml
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml	Escherichia coli	1.0x10^8 org/ml
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml	Moraxella catarrhalis	1.0x10^8 org/ml
Influenza B	3.16 x 10^6 $TCID_{50}$/ml	Neisseria lactamica	1.0x10^8 org/ml
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml	Nesseria subllava	1.0x10^8 org/ml
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/ml	Pseudomonas aeruginosa	1.0x10^8 org/ml
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml	Staphylococcus aureus subspaureus	1.0x10^8 org/ml
Measles	1.58 x 10^4 $TCID_{50}$/ml	Staphylococcus epidermidis	1.0x10^8 org/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml	Streptococcus pneumoniae	1.0x10^8 org/ml
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml	Streptococcus pygenes	1.0x10^8 org/ml
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml	Streptococcus salivarius	1.0x10^8 org/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml	Streptococcus sp group F	1.0x10^8 org/ml

INTERFERING SUBSTANCES TESTING

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

Description	Concentration
Mucin	2% w/v
Whole Blood	1% v/v
Sodium Chloride	5% w/v
Oxymetazoline	15% v/v
Zincum gluconium	5% w/v
peppermint	0.5% w/v
Fluconazole	5% w/v

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	STERILE R	Sterilised using irradiation

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

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