COVID/FLU A+B Ag FIA Rapid Test Device

Catalogue No.: FI2-RSPV-002

For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda COVID/FLU A+B Ag FIA Rapid Test Device is intended for *in vitro* detection of SARS-CoV-2 Nucleocapsid protein, influenza A and B antigens in nasopharyngeal swab specimens. This test is intended to aid in the differential diagnosis of SARS-Cov-2, influenza A and B viral infections.

TEST PRINCIPLE

The Biopanda COVID/FLU A+B Ag FIA Rapid Test Device detects Influenza A and Influenza B nucleoproteins based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains SARS-CoV-2 Nucleocapsid protein and/or influenza A and/or Influenza B nucleoproteins, it attaches to the fluorescent microspheres-conjugated anti-SARS-CoV-2 Nucleocapsid and/or anti-Influenza A and/or Influenza B antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of SARS-CoV-2 Nucleocapsid protein, Influenza A and/or Influenza B in the sample correlates with the fluorescence signal intensity captured on the test line (T), which can be scanned by the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). The testing results will be displayed on the analyser screen.

REAGENTS

The test contains anti-SARS-CoV-2 Nucleocapsid, anti-Influenza A and B conjugated fluorescence microspheres and anti-SARS-CoV-2 Nucleocapsid, anti-Influenza A and B coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
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 samples by using a new sample collection container for each sample obtained.
4. Do not eat, drink or smoke in the area where the samples and tests are handled. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of samples. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. Do not interchange or mix reagents or ID cards from different lots.
6. Extremes of humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The test should only be used with the analyser by medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT CONTENTS

Provided:

- 25 x Foil wrapped test devices
- 25 x Extraction tubes and tube tips
- 25 x Sterile swabs
- 1 x Extraction reagent bottle
- 1 x ID card
- 1 x Workstation
- 1 x Package Insert

Required but not provided:

- Timer
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SAMPLE COLLECTION AND PREPARATION

Nasopharyngeal Swab Sample 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.

Preparation:

Before performing the test, please bring the sample to room temperature (15-30°C). Cold buffer solution or moisture condensation on the test membrane can lead to invalid test results.

Transport and Storage:

Specimens should be tested as soon as possible after collection.
If swabs are not been processed immediately, it is highly recommended for the swab sample to be placed in a dry, sterile, and tightly sealed plastic tube for storage. In this condition, the swab specimen is stable for up to 24 hours at 2-8°C.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device User Manual for the complete instructions on use of the analyser. The test should be conducted at room temperature.

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

1. Turn on the Analyser.
2. Take out the ID card and insert it into the ID Card Slot. Choose test mode and/or sample type accordingly.
3. Take an extraction tube and place it the designated area of the workstation.
4. Take the extraction reagent bottle and squeeze **10 drops of buffer** (approx. 350 µl) into the extraction tube. Try not to touch the edge of the tube so the buffer drops fall freely.
5. Place the swab specimen into the extraction tube and rotate to swab head against the bottom of the tube for **about 10 seconds.** Remove the swab while squeezing the swab head against the tube to expel as much liquid as possible. **Discard swab in accordance with proper disposal protocol.**
6. Fit the tube tip on top of the extraction tube.
7. Remove the test Device from the sealed foil pouch and place it on a clean, level surface. Testing should start within one hour of opening the foil pouch.
8. Add **3 drops of solution** (approx. 75-100 µl) to the sample well of the test Device, and then start the timer.
9. **Test results should be interpreted at 15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

Note: There are different test modes for the Biopanda Fluorescence Immunoassay. Please consult the user manual prior to use to become familiar with the process and quality control procedures.

INTERPRETATION OF RESULTS

The test result is calculated by the Biopanda Fluorescence Immunoassay Device and displayed on the analyser screen. For additional information please refer to the user manual.

The result displayed on the analyser screen is given as Positive (+) or Negative (-) with a value. This value is calculated by dividing the signal obtained with the sample by the cut-off value (S/C Ratio).

Covid-19 Antigen:

- Test results with a value of ≥1.00 are considered positive for SARS-CoV-2.
- Test results with a value of <1.00 are considered negative for SARS-CoV-2.

Influenza A+B:

- Test results with a value of ≥1.00 are considered positive for Influenza A and/or B.
- Test results with a value of <1.00 are considered negative for Influenza A and/or B.

QUALITY CONTROL

Each 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 to display on the analyser.

Insufficient sample 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.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity, and Accuracy

The Biopanda COVID/FLU A+B Ag FIA Rapid Test Device has been evaluated with specimens obtained from the patients and compared to RT-PCR as a reference. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Covid-19 Test

		RT-PCR		Total
		Positive	Negative	
Biopanda Covid-19 Antigen	Positive	102	3	105
	Negative	3	314	317
Total		105	317	422
Relative Sensitivity		97.14%		
Relative Specificity		99.05%		
Accuracy		98.58%		

Influenza A+B Test

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Biopanda Flu A+B	Positive	92	2	94	82	2	84
	Negative	2	153	155	1	169	170
Total		94	155	249	83	171	254
Relative Sensitivity		97.87%			98.80%		
Relative Specificity		98.71%			98.83%		
Accuracy		98.39%			98.82%		

Reactivity with Human Influenza Strains

The Biopanda COVID/FLU A+B Ag FIA Rapid Test Device was tested with the following human influenza strains and a discernible line at appropriate test-line regions was observed:

Influenza A Virus		Influenza B Virus
A/NWS/33 10(H1N1)	A/chicken/Yuyao/2/2006 (H5N1)	B/R5
A/Hong Kong/8/68(H3N2)	A/swine/Hubei/251/2001 (H9N2)	B/Russia/69
A/Port Chalmers/1/73(H3N2)	A/Duck/Hubei/216/1983(H7N8)	B/Lee/40
A/WS/33(H1N1)	A/Duck/Hubei/137/1982(H10N4)	B/Hong Kong/5/72
A/New Jersey/8/76(HswN1)	A/Anhui/1/2013 (H7N9)	
A/Mal/302/54(H1N1)		

Specificity Testing with Various Viral Strains

Description	Test Level	Description	Test Level
Adenovirus Type 3	3.16 x 10^4 TCID50/ml	Mumps	1.58 x 10^4 TCID50/ml
Adenovirus Type 7	1.58 x 10^5 TCID50/ml	Sendai virus	8.89 x 10^7 TCID50/ml
Adenovirus type 10	3.16 x 10^3 TCID50/ml	Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Adenovirus type 18	1.58 x 10^4 TCID50/ml	Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Human coronavirus 229E	5.0 x 10^5 TCID50/ml	Respiratory syncytial virus	8.89 x 10^4 TCID50/ml
Human coronavirus HKU1	1.0 x 10^6 TCID50/ml	Human respiratory syncytial virus	1.58 x 10^5 TCID50/ml
Human coronavirus NL63	1.0 x 10^6 TCID50/ml	Rubella	2.81 x 10^5 TCID50/ml
Human coronavirus OC43	1.0 x 10^6 TCID50/ml 2.45 x 10^6 LD50/ml	Varicella-Zoster	1.58 x 10^3 TCID50/ml
MERS coronavirus Florida	1.17 x 10^6 TCID50/ml	Moraxella catarrhalis	1.0 x 10^8 org/ml
Coxsackievirus A9	2.65 x 10^4 LD50/ml 1.58 x 10^5 TCID50/ml	Neisseria lactamica	1.0 x 10^8 org/ml
Coxsackievirus B5	1.58 x 10^7 TCID50/ml	Neisseria subflava	1.0 x 10^8 org/ml
Human herpesvirus 2	2.81 x 10^5 TCID50/ml	Pseudomonas aeruginosa	1.0 x 10^8 org/ml
Human herpesvirus 5	1.58 x 10^4 TCID50/ml	Staphylococcus aureus subspaureus	1.0 x 10^8 org/ml
Human adenovirus B	1.58 x 10^4 TCID50/ml	Staphylococcus epidermidis	1.0 x 10^8 org/ml
Human adenovirus C	5.62 x 10^5 TCID50/ml	Streptococcus pneumoniae	1.0 x 10^8 org/ml
Echovirus 2	3.16 x 10^5 TCID50/ml	Streptococcus pyogenes	1.0 x 10^8 org/ml
Echovirus 3	1 x 10^4 TCID50/ml	Streptococcus salivarius	1.0 x 10^8 org/ml
Echovirus 6	3.16 x 10^6 TCID50/ml	Streptococcus sp group F	1.0 x 10^8 org/ml
Herpes simplex virus 1	1.58 x 10^6 TCID50/ml	Arcanobacterium	1.0 x 10^8 org/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml	Candida albicans	1.0 x 10^8 org/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml	Corynebacterium	1.0 x 10^8 org/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml	Escherichia coli	1.0 x 10^8 org/ml
Measles	1.58 x 10^4 TCID50/ml		

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Endogenous Interfering Substances

The following potentially Interfering Substances were added to the Biopanda COVID-19 Antigen/Influenza A+B negative and positive specimens and showed no interference.

Active Ingredient	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

Precision

Intra-assay and Inter-assay

Within-run precision has been determined by using 10 replicates of three specimens of negative, medium positive, and high positive controls. The specimens were correctly identified >99% of the time.

Between-run precision has been determined by using 10 independent assays on the same three specimens of negative, medium positive, and high positive controls. The specimens were correctly identified >99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10^8org/ml and all found to be negative when tested with the Biopanda COVID/FLU A+B Ag FIA Rapid Test Device:

Arcanobacterium
Candida albicans
Corynebacterium
Enterococcus faecalis
Enterococcus faecium
Escherichia coli
Haemophilus
Moraxella catarrhalis
Neisseria gonorrhoeae
Neisseria lactamica
Nesseria subllava
Proleus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus subspaureus
Staphylococcus epidermidis
Staphylococcus saprophylicus
Streptococcus agalactiae
Streptococcus bovis
Streptococcus dysgalatiae/subsp.dysgalatiae
Streptococcus oralis formerly Streptococcus
Streptococcus pneumoniae
Streptococcus pygenes
Streptococcus salivarius
Streptococcus sp group F.type 2

LIMITATIONS OF THE TEST

1. The Biopanda COVID/FLU A+B Ag FIA Rapid Test Device is for professional *in vitro* diagnostic use, for the qualitative detection of SARS-CoV-2 Nucleocapsid protein, Influenza A and/or B virus in nasopharyngeal swab specimens.
2. The test will only indicate the presence of SARS-CoV-2 Nucleocapsid protein, influenza A and/or B virus in the specimen and should not be used as the sole criteria for diagnosis.
3. Proper specimen collection, storage and transport are critical to the performance of this test. Failure to follow the procedure may give inaccurate results. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may field a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

Thank you for purchasing Biopanda's COVID/FLU A+B Ag FIA Rapid Test Device kit. Please read this manual carefully before operating to ensure proper use.

Biopanda Reagents Ltd.
Unit 14 Carrowreagh Business Park
Carrowreagh Road
Belfast, BT16 1QQ
United Kingdom
Tel: +44 (0) 28 95438774
E-mail: info@biopanda.co.uk
Website: www.biopanda.co.uk

Revision Date: 31/03/2025
PI-FI2-RSPV-002