RSV FIA Rapid Test Device

Catalogue No.: FI2-RSV-001

A Fluorescence Immunoassay test for the qualitative detection of Respiratory Syncytial Virus Antigen in human nasopharyngeal swab or nasal aspirate specimens with the use of Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda RSV FIA Rapid Test Device is intended for *in vitro* qualitative detection of Respiratory Syncytial Virus Antigens (RSV*)* in nasopharyngeal swab or nasal aspirate specimens. This test is intended to aid in the diagnosis of Respiratory Syncytial Virus infections.

SUMMARY

Respiratory Syncytial Virus (commonly known as 'RSV'), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill. But in premature babies and children with diseases that affect the lungs, heart, or immune system, RSV infections can lead to other more serious illnesses.[1] RSV is highly contagious and can be spread through droplets containing the virus when someone coughs or sneezes. It also can live on surfaces (such as countertops or doorknobs) and on hands and clothing, so it can be easily spread when a person touches something contaminated. RSV can spread rapidly through schools and childcare centers. Babies often get it when older kids carry the virus home from school and pass it to them. Almost all kids are infected with RSV at least once by the time they're 2-3 years old. RSV infections often occur in epidemics that last from late fall through early spring. Respiratory illness caused by RSV such as bronchiolitis or pneumonia-usually lasts about a week, but some cases may last several weeks.

The RSV FIA Rapid Test Device qualitatively detects the presence of Respiratory Syncytial Virus antigen in human nasopharyngeal swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Respiratory Syncytial Virus to selectively detect Respiratory Syncytial Virus antigen in human nasopharyngeal swab or nasal aspirate specimens.

TEST PRINCIPLE

The RSV FIA Rapid Test Device detects Respiratory Syncytial Virus nucleoproteins based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Respiratory Syncytial Virus nucleoproteins, it attaches to the fluorescent microspheres-conjugated anti-Respiratory Syncytial Virus antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Respiratory Syncytial Virus in the sample correlates with the fluorescence signal intensity captured on the T line, which can be read by the Biopanda Fluorescence Immunoassay Analyser. The testing results will be displayed on the analyser screen.

REAGENTS

The test contains anti-RSV conjugated fluorophores and anti-RSV 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 Biopanda RSV FIA Rapid Test should only be used with the Biopanda Fluorescence Immunoassay Device 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 COMPONENTS

Provided:

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

Required but not provided:

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

SAMPLE COLLECTION AND PREPARATION

Collection:

Nasopharyngeal Swab Sample

- 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.

Nasal Aspirate Sample

Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device. Insert the catheter to nasal cavity from a nostril, start the aspiration device and then collect a nasal aspirate sample. Dip a sterilized swab into the collected nasal aspirate sample, ready for sample extraction.

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.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test, specimen, 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. 400 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 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. 120 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 Analyser.

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.

NOTE: 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).

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

QUALITY CONTROL

Each RSV FIA Rapid Test Device 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 RSV FIA Rapid Test Device has been evaluated with specimens obtained from patients. RT-PCR is used as the reference method for the RSV FIA Rapid Test Device. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

		RT-PCR		
		Positive	Negative	**Total**
RSV FIA Rapid Test Device	Positive	60	6	66
	Negative	4	103	107
Total		64	109	173
Relative Sensitivity		93.75% (95%CI*:84.76%~98.27%)		
Relative Specificity		94.50% (95%CI*:88.40%~97.95%)		
Accuracy		94.22% (95%CI*:89.63%~97.19%)		

*Confidence Intervals

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using three specimens of Respiratory Syncytial Virus standard control. Three different lots of the RSV FIA Rapid Test Device have been tested using negative, weak positive, strong positive specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

The following substances do not interfere with the RSV FIA Rapid Test Device: Whole Blood, Mucin, Sinus Buster Nasal Spray, NeoSynephrine Cold & Sinus Extra Strength Spray, Zicamn Extreme Congestion Relief, Albuterol, 4-Acetamidophenol, Acetylsalicylic Acid, Chlorpheniramine, Dexamethasone, Dextromethorphan, Diphenhydramine, Doxylamine Succinate, Ephedrine, Flunisolide, Guaiacol glyceryl ether, Mupirocin, Oxymetazoline, Rebetol, Phenylephrine, Relenza, Rimantadine, Tamiflu, Tobramycin, Triamcinolone.

Cross-reactivity

No cross reaction has been confirmed of the RSV FIA Rapid Test Device with the following pathogens:

Bacteria

Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum, Escherichia coli, Group C streptococcus, Group G streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria gonorrhoeae, Peptococcus asaccharolyticus, Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae (group B), Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes (group A), Veillonella parvula.

Viral

Influenza A, Influenza B, Adenovirus Type 1~8,11,19,37, Coxsackie virus Type A16, B1~5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus, Type I simple herpes virus, Parainfluenza virus Type 1~3, Poliovirus Type 1~3, Rhinovirus Type 1A,13,14.

Mycoplasma etc.

No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis, Mycoplasma pneumoniae.

LIMITATIONS OF THE TEST

1. The RSV FIA Rapid Test Device is for professional *in vitro* diagnostic use only. The test should be used for the qualitative detection of RSV virus in nasopharyngeal swab or nasal aspirate specimens.
2. The RSV FIA Rapid Test Device will only indicate the presence of RSV virus in the specimen from both viable and non-viable RSV strains.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. The RSV Test Cassette is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with Respiratory Syncytial Virus.
5. Excess mucus on the swab specimen may interfere with test performance and may yield 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. The results of RSV Tests are based on measuring the levels of RSV in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

REFERENCES

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.

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		Do not use if package is damaged

Thank you for purchasing Biopanda's RSV FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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