Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD F

RSV Ag FIA

STANDARD™ F RSV Ag FIA

REF FRSV01G

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

[Introduction]

RSV (Respiratory syncytial virus) is an enveloped, negative-sense RNA virus belonging to the *Paramyxoviridae* family. It occurs throughout the world, and in each location it tends to occur in yearly winter outbreaks. The virus lives inside the cells lining the respiratory system, causing swelling of this lining coupled with the production of large amounts of excess mucus. In adults, this shows up as a bad, lingering cold with thick nasal congestion and a deep, productive cough. In infants, however, the excess mucus can be enough to plug their small airways or bronchioles, resulting in a severe illness called bronchiolitis that requires hospitalization. Children who first get it under 6 months of age or who have serious underlying illnesses are at the highest risk for severe disease. A serious RSV infection is a frightening experience for parents and their baby and one of the most severe public health problems worldwide. Therefore, rapid and accessible detection of RSV is important for efficient prevention and prompt treatment of it. STANDARD F RSV Ag FIA, employing immunofluorescent detection system with STANDARD F analyzer, provides significantly fast, easy and accurate system to identify the target antigen from nasopharyngeal swab or nasopharyngeal aspirate/wash specimens. The test may aid in the reliable clinical diagnosis of RSV and enables supportive treatment decisions.

[Intended use]

STANDARD F RSV Ag FIA is the fluorescence immunoassay to detect RSV antigen present in nasopharyngeal swab or nasopharyngeal aspirate/wash specimens from patients with symptoms of a viral respiratory infection. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of RSV infection. It provides only an initial screening test result. Specific alternative diagnosis method should be performed in order to obtain the confirmation of the infection.

[Test principle]

STANDARD F RSV Ag FIA is based on immunofluorescence technology with STANDARD F analyzer to detect RSV antigen. For extraction of the viral antigen, the patient's specimens is put into the extraction tube containing the extraction buffer. After extraction, extracted specimen is applied into the sample well of the test device and specimen migrates through the membrane from the sample well. If RSV antigen is present, it will be bound to by monoclonal anti-RSV coupled to europium microparticle that migrates through the membrane. The fluorescent microparticle containing RSV antigen will be captured by monoclonal anti-RSV on the test line where it is detected by STANDARD F analyzer. If RSV antigen is not present, the europium microparticle will not be trapped by the capture antibody nor detected by STANDARD F Analyzer. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer. STANDARD F Analyzer can analyze the presence of the RSV antigen in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

KIT CONTENTS

① Test device ② Extraction buffer tube ③ Positive control ④ Negative control ⑤ Sterile swab
⑥ Fixed volume dropper(300µl) ⑦ Filter cap ⑧ Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. STANDARD F analyzer
2. Timer

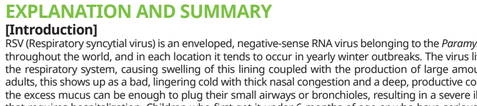
WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal isb roken.
3. Do not use extraction buffer of another lot.
4. Use the STANDARD F RSV Ag FIA at 15-32°C / 59-90°F and 10-90%RH.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
12. The barcode of the test device is used by analyzer to identify the type of test being run and to identify the individual test device so as to prevent to a second read of the test device by the same analyzer.
13. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again in the same analyzer.
14. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
15. Improper specimen collection, handling or transport may yield inaccurate results.
16. Do not write on the bar code or damage the bar code of the test device.

KIT STORAGE AND STABILITY

Store the kit at 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION



Nasopaharyngeal Swab | Nasopharyngeal Aspirate | Nasopharyngeal Wash (Syringe method) | Nasopharyngeal Wash (Bulb method)

[Nasopharyngeal swab]

1. To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx.
3. Rotate the swab a few times near the surface of the posterior nasopharynx then remove it.
4. After collection, immediately transport specimen to the laboratory for viral testing and viral antigen detection. If transport to the laboratory is delayed, place specimen on ice or in refrigeration.

[Nasopharyngeal aspirate]

1. With the patient's head hyper-extended, instill a few drops of sterile and normal saline into one nostril to be suctioned.
2. Insert the flexible plastic tubing along the nostril floor, parallel to the palate.
3. After entering the nasopharynx, aspirate the secretions while removing the tubing.
4. Repeat procedure for the second nostril will deliver optimal combined specimen.
5. After collection, immediately transport specimen to the laboratory for viral testing and viral antigen detection. If transport to the laboratory is delayed, place specimen on ice or in refrigeration.

[Nasopharyngeal wash]

1. Fill the syringe or aspiration bulb with the minimal volume of saline required per the subject's size and age.
2. Instill the saline into one nostril while the head is tilted back.
3. Aspirate the wash specimen back into the syringe or bulb.
4. Repeating procedure for the second nostril will deliver optimal combined specimen.
5. After collection, immediately transport specimen to the laboratory for viral testing and viral antigen detection. If transport to the laboratory is delayed, place specimen on ice or in refrigeration.

SPECIMEN STORAGE AND TRANSPORT

[Specimen storage]

1. Specimens should be tested as soon as possible after collection.
2. For prolonged storage, specimens should be kept refrigerated at 2-8°C / 36-46°F in a clean, dry, closed container for up to 4 days or 24 hours at room temperature at 15-30°C / 59-86°F.
3. Avoid multiple freeze-thaw cycles.

[Specimen in transport media]

1. Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system.
2. The BD Universal Viral Transport and Copan Universal Transport Medium have been tested and found to be compatible with STANDARD F RSV Ag FIA.
3. For nasopharyngeal swabs in transport media, a minimal volume of 1ml is recommended and for nasopharyngeal aspirate/wash, sample volumes of 1-3ml are recommended.

CAUTION

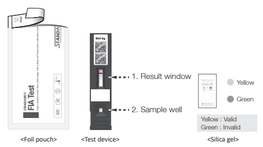
- Minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.

TEST PROCEDURE

[Preparation]

1. Allow the test device and collected specimen to room temperature prior to testing.
2. Carefully read the instruction for using the STANDARD F RSV Ag FIA.
3. Look at the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

4. Open the foil pouch, and check the test device and the silica gel pack inside the foil pouch.



CAUTION

- If a violet colored band (check band) does not appear in the result window of the test device, do not use it.

[Positive/negative control processing]

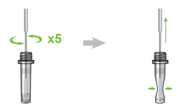
1. Insert the collected positive/negative swab to the tube with 300µl of extraction buffer.
2. Swirl the swab at least 5 times.
3. Remove the swab while squeezing the side if the tube to extract the liquid from the swab.
4. Discard the swab in accordance with your biohazard waste disposal protocol.

5. Screw the filter cap tightly onto the tube.

[Specimen processing]

- **Nasopharyngeal swab**

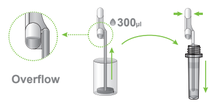
1. Insert the collected nasopharyngeal swab to the tube with 300µl of extraction buffer.
2. Swirl the swab at least 5 times.
3. Remove the swab while squeezing the side if the tube to extract the liquid from the swab.
4. Discard the swab in accordance with your biohazard waste disposal protocol.



5. Screw the filter cap tightly onto the tube.

- **Nasopharyngeal aspirate/wash or specimens in transport media**

1. Fill the dropper with sample mixture by firrmly squeezing the top bulb and slowly releasing the pressure, and then add entire 300µl of the specimen into the tube with 300µl of extraction buffer.



2. Gently mix the specimen mixture well.

3. Remove the dropper and screw the filter cap tightly onto the tube.

NOTE

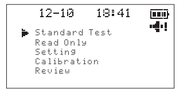
- Specimen and extraction buffer should be well mixed and then immediately apply the processed specimen mixture at the test device within 1 minute.
- Fixed volume dropper is designed to aspirate/wash the correct amount of solution by collecting overflowed liquid in the bottom bulb of droppers.

[Analyzing the test results]

- **STANDARD F 100 Analyzer**

- **'Standard Test' mode**

1. Prepare the analyzer and set the `Standard Test' mode according to the manual.



2. Insert the test device to the analyzer. The analyzer automatically allows the test device to read the information of the test device and release the test device for adding specimen mixture.

3. Inverting and holding the tube vertically, squeeze gently allowing 4 drops of the processed specimen mixture to be dispensed into the sample well of test device.

4. **After applying, press the start button immediately.**

5. The analyzer allows the test device to develop within 15 minutes.

6. The analyzer will automatically display the test result on the screen.

NOTE

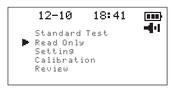
- Strong positive results may be observed after 5 minutes.

- **'Read Only' mode**

1. Inverting and holding the tube vertically, squeeze gently allowing 4 drops of the processed specimen mixture to be applied to the sample well of test device.

2. Leave the test device for 15 minutes outside the analyzer for incubation.

3. Prepare the analyzer and set the 'Read Only' mode according to the manual.



4. Once the incubation time is complete, insert the test device into the analyzer.

5. The analyzer will automatically display the test result on the screen.

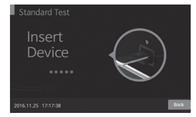
- **STANDARD F 200 Analyzer**

- **'Standard Test' mode**

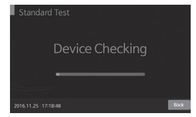
1. Prepare the analyzer and select the 'Standard Test' mode on the screen according to the manual.

2. Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer with touching 'Direct', the analyzer will regard the test as that of the guest.

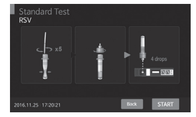
3. Insert the test device into the analyzer's test slot.



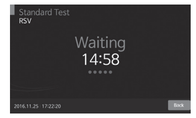
4. When inserting the test device to the analyzer, the analyzer will automatically check whether it is used or not. Also, the analyzer read the bar code data, and check the test device is valid.



5. Apply 4 drops of specimen mixture into the sample well of the test device.
6. **After applying, press the start button immediately.**



7. The analyzer allows the test device to develop for 15 minutes.



8. The analyzer will automatically display the test result on the screen.

NOTE

- Strong positive results may be observed after 5 minutes.

- **'Read Only' mode**

1. Inverting and holding the tube vertically, squeeze gently allowing 4 drops of the processed specimen mixture to be applied to the sample well of test device.

2. Leave the test device for 15 minutes outside the analyzer for incubation.

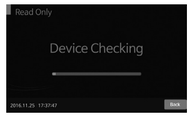
3. Prepare the analyzer and select the 'Read Only' mode on the screen according to the manual.

4. Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer with touching 'Direct', the analyzer will regard the test as that of the guest.

5. Insert the test device into the analyzer's test slot.

SD BIOSENSOR

6. When inserting the test device to the analyzer, the analyzer will automatically check whether it is used or not. Additionally, the analyzer read the bar code data, and check the test device is valid.



7. The analyzer will automatically display the test result on the screen.

CAUTION

- The mark on the label between sample well and result window is scanned by the STANDARD F200 Analyzer and displayed on the screen.

INTERPRETATION OF TEST RESULTS

[Displays of STANDARD F100 Analyzer]

STANDARD F100 Analyzer	
Test result	**Window example**
Negative	12-10 18:41 RSV : Neg(-) COI=0.000
Positive	12-10 18:41 RSV : Pos(+) COI=1.234
Invalid	12-10 18:41 INVALID Device

[Displays of STANDARD F200 Analyzer]

STANDARD F200 Analyzer	
Test result	**Window example**
Negative	
Positive	
Invalid	

NOTE

The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. COI is calculated that a measured signal is divided by an appropriate cutoff value.
- Test results of a COI ≥ 1.00 are considered positive for RSV Antigen.
- Test results of a COI < 1.00 are considered negative for RSV Antigen.

QUALITY CONTROL

[Calibration]

The calibration set test of STANDARD F analyzer should be conducted according to the analyzer's manual.

• When to use calibration set

1. Before using the analyzer for the first time.
2. When you drop the analyzer.
3. Whenever you do not agree with your result.
4. When you want to check the performance of an analyzer and test device.

• How to use calibration set

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' in main menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

NOTE

- The STANDARD F analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

[Internal quality control]

1. The internal procedural control zone is on the membrane of the test device. STANDARD F analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F analyzers. shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

[External quality control]

1. Positive and negative controls are also supplied with each kit and these controls are provided as a means of additional quality control to demonstrate a positive or negative reaction.
2. SD BIOSENSOR recommends that positive and negative controls be run:
   - Once for each new lot.
   - Once for each untrained operator.
   - As required by internal instructions for use for STANDARD F RSV Ag FIA and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATION OF THE TEST

1. The contents of this kit are to be used the qualitative detection of RSV antigen from nasopharyngeal swab, aspirate or wash of the symptomatic patients.
2. Failure to follow the test procedure and interpretation of test result may adversely affect test performance or invalidate the test result.
3. Positive test results cannot exclude co-infections with other pathogens.
4. Negative test results cannot exclude possible other non-RSV viral infections.
5. Negative test results can occur if the quantity of RSV antigens present in the specimen is below the detection limits of the assay, or the detected antigens are not present during the stage of disease in which a specimen is collected.
6. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low RSV activity when prevalence is moderate to low.
7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.

BIBLIOGRAPHY

1. Hall CB, Schnabel KC, Gieman JM, Douglas RC. Infectivity of respiratory syncytial virus by various routes of inoculation. Infect Immun. 1981; 33: 779-783.
2. Hall CB, and Douglas RG Jr. Modes of transmission of respiratory syncytial virus. J Pediatr. 1981; 99(1):100-103.
3. Macartney K.et al. Nosocomial Respiratory Syncytial Virus Infections: The Cost-Effectiveness and Cost-Benefit of Infection Control. Pediatrics. 2000; 106(3):520.
4. Falsey AR, Hennessey PA, Formica MA, Cox C, Walsh EE. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med. 2005; 352(17):1749-59.

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE

Manufactured by SD BIOSENSOR
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

Any inquiries provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L28RSV1ENR4
Issue date : 2017.11

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
Do not re-use.
To indicate the temperature limitations in which the transport package has to be kept and handled.
Use by
LOT Batch code
Manufacturer
Date of manufacture
Indicate the date of manufacture for this analyzer
Note