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

STANDARD F

Adeno Respi Ag FIA

REF F-ARS-01

STANDARD™ F Adeno Respi Ag FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]

Human adenoviruses are a large group of viruses, represented by at least 52 serotypes with various genotypes divided into genomic clusters, and these are important human pathogens which are responsible for several types of diseases, especially in children and in young adults.
Adenoviruses has been implicated in respiratory, gastrointestinal, ophthalmologic, genitourinary, neurologic, and disseminated disease. Respiratory tract adenovirus infection manifests itself in various clinical forms including pharyngitis, bronchitis, exudative tonsillitis, pharyngoconjunctival fever, and pneumonia. 1Many of these infections are difficult to distinguish clinically from other respiratory virus infections and some bacterial infections. Laboratory diagnostics, such as cell culture and viral serological tests, are generally required to identify the etiology.
STANDARD F Adeno Respi Ag FIA, containing a highly specific and sensitive antibody, provides significantly fast, easy and accurate system to identify the target antigen in a nasopharyngeal specimen.

[Intended use]

The STANDARD F Adeno Respi FIA is the fluorescence immunoassay to detect adenovirus infection in human nasal swab and nasopharyngeal swab, identifying existence of adenovirus. STANDARD F Adeno Respi FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This is intended for professional use, only for an initial screening test.

[Test principle]

The rapid test membrane of STANDARD F Adeno Respi FIA is coated with monoclonal anti-ADENOVIRUS on the test line. For the test, the sample is added to the sample well and interacts with monoclonal anti-ADENOVIRUS-EP on the conjugate pad. The antigens in sample and the europium conjugated antibodies make complexes and moves along membrane to the control and test line chromatographically to react with the antibodies coated on the surface of membrane. If Adenovirus are present in sample, the Adenovirus combined with monoclonal anti-ADENOVIRUS-EP are captured on the test line make a fluorescence signal. The fluorescence signal is measured using the fluorescence signal of the control line as the procedural control.
STANDARD F Adeno Respi FIA is read by the specific analyzer called STANDARD F Analyzer manufactured by SD BIOSENSOR, Inc. The analyzers use the fluorescence sensor to measure reflected light from the membrane of the test device. The intensity of the reflected light is scanned and converted into an electric signal which is proportional to the intensity of reflected light produced on the membrane. STANDARD F analyzer can calculate the concentration of the analysis in the clinical specimen based on a pre-programmed calibration curve and display the test result on the screen.

[Kit contents]

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

[Materials required but not provided]

- STANDARD F Analyzer
- Timer

KIT STORAGE AND STABILITY

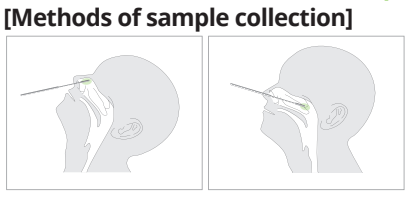
Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

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 is broken.
3. Do not use the extraction buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Do not use the test kit beyond the expiration date.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly when 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. Immediately use the test device after taking out of aluminum foil pouch.
13. If the test result with positive/negative control swab is abnormal, do not use the kit.
14. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
15. The bar code 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.
16. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again in the same analyzer.
17. Improper specimen collection, handling or transport may yield inaccurate results.
18. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN PREPARATION, STORAGE AND TRANSPORT

[Methods of sample collection]



Nasal Swab | Nasopharyngeal Swab

[Specimen preparation]

- **Nasal swab**

1. To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril).
3. Rotate the swab a few times against the nasal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at refrigerated (2-8°C/36-46°F) or at room temperature (15-30°C/59- 86°F), in a clean, dry, closed container for up to 48 hours at refrigerated (2-8°C / 36-46°F) or 24 hours at room temperature (15-30°C / 59-86°F) prior to testing.

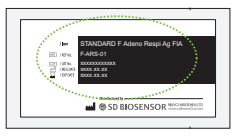
- **Nasopharyngeal swab**

1. To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinate.
3. Rotate the swab a few times against the nasopharyngeal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours in a clean, dry, closed container prior to testing.

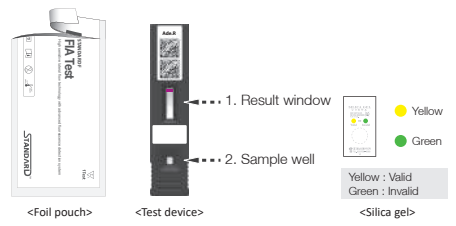
TEST PROCEDURE

[Preparation]

1. Allow test device and collected sample to room temperature (15-30°C/59-86°F) prior to testing.
2. Carefully read the instructions for using the STANDARD F Adeno Respi Ag FIA.
3. Check 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 in the foil pouch.



<Foil pouch> <Test device> <Silica gel>

CAUTION

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

CAUTION

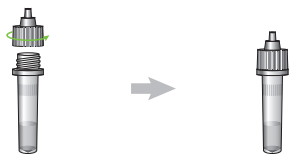
- Do not write on the bar code or damage the bar code of the test device.

[Collection of sample]

- **Nasal/nasopharyngeal swab**

1. Allow test device to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Insert the nasopharyngeal swab sample of patient into an extraction buffer tube. Swirl the swab at least five times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.

4. Tightly screw the filter cap onto the tube.
5. Snap the tip of the filter cap through the breakpoint of the tip.



CAUTION

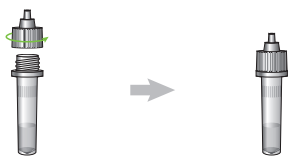
- Using the nasopharyngeal swab sample may result the weak immune reaction with Adenovirus in patient sample and the anti-Adenovirus in the device because of the over dilution of the sample.

- **Positive/Negative control**

To test external quality control, follow the procedures for nasopharyngeal swab sample with the positive and negative control swab in the kit instead of the collected nasopharyngeal swab sample.

1. Insert the positive/negative control swab in the kit into an extraction buffer tube. Swirl the swab at least five times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.

3. Tightly screw the filter cap onto the tube.



[Analysis of sample]

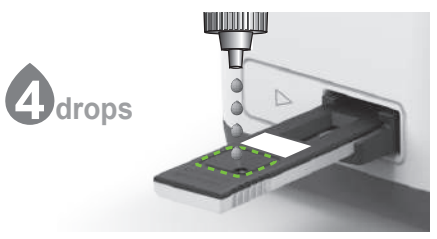
There are two ways of test procedure by using analyzers as following method; 'STANDARD TEST mode', 'READ ONLY mode'. 'STANDARD TEST mode' may be most convenient for reading a single patient sample, as the user can walk away during the development period. 'READ ONLY mode' have an advantage when the large numbers of the sample should be tested with the STANDARD F analyzer in a short time as the user read the results sequentially.

- **Using a 'STANDARD TEST' mode**
  - **Applying of STANDARD F100, F200 and F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'.
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.
4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.

SD BIOSENSOR

5. Apply 4 drops of mixed sample to the sample well in the test device.



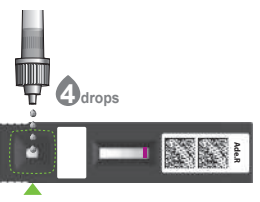
6. After applying the sample, immediately press the **'TEST START'** button.

<F100> <F200> <F2400>

7. The analyzer will automatically display the test result within 15 minutes.

- **Using a 'READ ONLY' mode**
  - **Applied STANDARD F100 and F200 analyzer**

1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a sample information on the label of test device.
2. Apply 4 drops of mixed sample to the sample well in the test device.



3. Incubate the test device for 15 minutes outside of the analyzer. Incubation must not be more than 20 minutes.

4. Prepare a STANDARD F Analyzer and select the 'Read Only' mode according to the analyzer's manual. Insert the test device to the test slot of the analyzer.
5. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	Positive for Adenovirus
Negative	COI < 1.0	Negative for Adenovirus
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient sample

NOTE

The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI(cutoff index) value. The COI is a numerical representation of the measured fluorecence signal.

QUALITY CONTROL

[STANDARD F Analyzers calibration check]

The calibration set test of STANDARD F Analyzers 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' 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.

CAUTION

- The STANDARD F100 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 procedural control]

1. The internal procedural control zone is in the end of 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 may be supplied with each kits or can be purchased from the distributors.
2. It is recommended that positive and negative controls be run:
   - once for each new lot.
   - once for each untrained operator.
   - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of adenovirus in the specimen and should not be used as the sole criteria for the diagnosis of adenovirus infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate of adenovirus concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

BIBLIOGRAPHY

1. Berk, A, Knipe, DM, Howley, PM. "Adenoviridae: the viruses and their replication". Fields virology. vol. 2. Wolters Kluwer/ Lippincott Williams and Wilkins. 2007. pp. 2355-94.
2. Choi EH, Lee HJ, Kim SJ, Eun BW, Kim NH, Lee JA, Lee JH, Song EK, Kim SH. (2006). Ten year analysis of adenovirus type 7 molecular epidemiology in Korea, 1994-2004: Implication of fiber diversity. J. Clin. Virol. 35(4):388-393.
3. HYPERLINK "https://www.ncbi.nlm.nih.gov/pubmed/?term=Echavarr%26%23x000ed%3Ba%20M%5BAuthor%5D&cauthor=true&cauthor_uid=18854488" Marcela Echavarría , Adenoviruses in Immunocompromised Hosts. HYPERLINK "https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2570151/" Clin Microbiol Rev. 2008 Oct; 21(4): 704–715.

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.

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 | CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices | Manufacturer | Date of manufacture | Irritant | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged