STANDARD F Strep A Ag FIA

STANDARD™ F Strep A Ag FIA
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

[Introduction]
Group A streptococcus (GAS) is a bacterium commonly found in the respiratory, alimentary, and genital tracts, as well as in the skin and mucous membrane. Group A streptococcus is spread through direct contact with nasal or throat secretions of an infected person or through contact with infected skin sores or drainage from wounds. Most group A streptococcal infections are self-limiting and amenable to antibiotics. On rare occasions, these bacteria can cause invasive infections and even life-threatening disease when breaks in the skin or in the oral mucosa allow the bacteria to enter the tissue or when the patient has a chronic disease or compromised immune system that weakens the defenses against bacteria. Two of the most serious forms of invasive group A streptococcal disease are necrotizing fasciitis and streptococcal toxic shock syndrome (STSS). Necrotizing fasciitis rapidly destroys muscles, fat, and skin tissue. Streptococcal toxic shock syndrome causes blood pressure to drop rapidly and organs to fail. Less serious invasive diseases caused by group A streptococci include cellulitis and pneumonia. While 10%-15% of patients with invasive group A streptococcal (GAS) disease die from the infection, approximately 25% of patients with necrotizing fasciitis and more than 50% with streptococcal toxic shock syndrome die.

[Preparation]

1. Allow kit components and specimen to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to use.
2. Carefully read instructions for using the STANDARD F Strep A Ag FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot if the expiry date has passed.
4. Check the Extraction buffer 1 and buffer 2 as the picture on the side.
5. Open the foil pouch, and check the test device and the stick get pack in the foil pouch.

[Test principle]
STANDARD F Strep A Ag FIA is based on immunofluorescence technology with STANDARD F analyzer to detect group A streptococcus (Strep A) antigen in the clinical specimen. It provides only an initial screening test result. Specific alternative diagnostic method should be performed in order to confirm the grouping of group A streptococcal infection.

[Materials required but not provided]
- STANDARD F analyzer
- Timer

[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.

[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 re-use extraction buffer 1 or extraction buffer 2 of another lot.
4. Do not store, drink or eat while handling specimen.
5. Wear personal protective equipment such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.

[Specimen collection, preparation and storage]

[Throat swab]
1. Open the mouth widely.
2. Depress the tongue with a tongue blade or spoon.
3. Rub the swab on the back of the throat, both of the tonsils, the uvula and the posterior pharynx.
4. Be careful not to touch the tongue, sides or top of the mouth with the swab.
5. Swabs should be stored at room temperature for up to 24 hours or at 2-8°C/36-46°F for up to 48 hours after collection in a clean and dry plastic tube.

[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 Strep A Ag FIA.

CAUTION
① Minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.

TEST PROCEDURE

[Analysis of sample]

- Using a 'STANDARD Test' mode
  - Applying of STANDARD F 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 F100 and F200 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.
    5. Press the top buls of a disposable dropper (100μl) and place the tip of the pipette into the prepared sample.

- Enzyme Immunoassay (EIA) for the detection of group A streptococcus (Strep A) antigen
  1. Add 3 drops of extraction buffer 2 into the extraction buffer 1.
  2. Put the Throat swab into the extraction buffer tube, and the incubate for about 1 minute to extract the specimen from the swab.
  3. Sift the swab at least 10 times while pressing the head against the bottom and side of the tube.
  4. Roll the swab head against the inside of the test tube as you remove it.
  5. Discard the swab in accordance with your laboratory waste disposal protocol.

- Analysis by Multi-arrayed Post-Test (MAPS)
  1. Use a STANDARD F analyzer, and select the 'MAPS 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 F100 and F200 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.
  5. Press the top buls of a disposable dropper (100μl) and place the tip of the pipette into the prepared sample.

[Artificially contaminated positive control]

- Using a 'STANDARD Test' mode
  1. In case of STANDARD F F100, go to the 'Workplace' in the main screen and select the 'Run Test'.
  2. Select the 'Run Test' in case of STANDARD F200 and F2400 analyzer.

[Negative control]

- Using a 'STANDARD Test' mode
  1. In case of STANDARD F F100, go to the 'Workplace' in the main screen and select the 'Run Test'.
  2. Select the 'Run Test' in case of STANDARD F200 and F2400 analyzer.

- Using a 'MAPS Test' mode
  1. In case of STANDARD F F100, go to the 'Workplace' in the main screen and select the 'Run Test'.
  2. Select the 'Run Test' in case of STANDARD F200 and F2400 analyzer.

[Sample processing]

1. Add 3 drops of extraction buffer 2 into the extraction buffer 1.
2. Put the Throat swab into the extraction buffer tube, and the incubate for about 1 minute to extract the specimen from the swab.
3. Sift the swab at least 10 times while pressing the head against the bottom and side of the tube.
4. Roll the swab head against the inside of the test tube as you remove it.
5. Discard the swab in accordance with your laboratory waste disposal protocol.

[Analysis of sample]

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  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 F100 and F200 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.

[Material required but not provided]
- STANDARD F analyzer
- Timer

[KIT STORAG AND STABILITY]
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2. The BD Universal Viral Transport and Copan Universal Transport Medium have been tested and found to be compatible with STANDARD F Strep A Ag FIA.

CAUTION
① Minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.
6. Collect the sample until the black line of the dropper (100μL).
7. Apply 100μl of specimen mixture to the sample well of the test device.
8. After applying the sample, immediately press the 'TEST START' button.
9. The analyzer will automatically display the test result within 5 minutes.

• Using a 'READ ONLY' mode
• Applying of STANDARD F 1F00 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. Compress the top bulb of a disposable dropper (100μl) and place the tip of the pipette into the prepared sample.
  3. Collect the sample until the black line of the dropper (100μl).
  4. Apply 100μl of specimen mixture to the sample well of the test device.
  5. Incubate the test device for 5 minutes outside of the analyzer.
  6. Prepare a STANDARD F Analyzer and select the ‘Read Only’ mode according to the analyzer’s manual.
  7. Insert the test device to the test slot of the analyzer.
  8. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.

INTERPRETATION OF TEST RESULTS

<table>
<thead>
<tr>
<th>Result</th>
<th>COD (Cut-off index) Value</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>&gt; 1.0</td>
<td>Positive for Strept A antigen</td>
</tr>
<tr>
<td>Negative</td>
<td>&lt; 1.0</td>
<td>Negative for Strept A antigen</td>
</tr>
<tr>
<td>Invalid</td>
<td>Not show the COD value</td>
<td>Result should be performed</td>
</tr>
</tbody>
</table>

The test result of a sample is given either as Positive/Positive or Negative/Negative with a COD cut-off index value. The COD is a numerical representation of the measured fluorescence signal.

QUALITY CONTROL
[Calibration]

The calibration test set 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 stop 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 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.

BIBLIOGRAPHY

Product Disclaimer
While 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 from or related to an incorrect diagnosis, whether positive or negative, error, or use of this product.