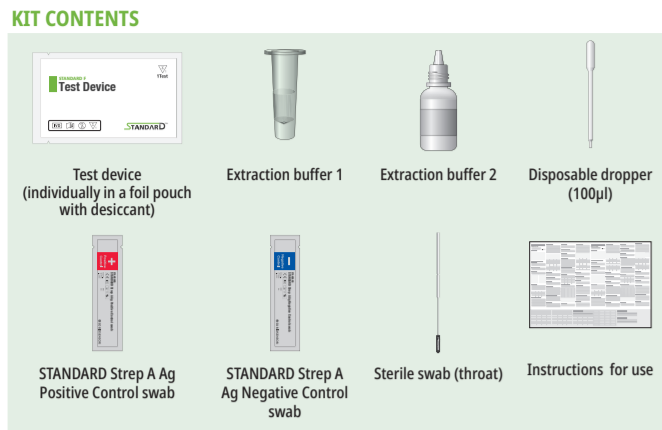


STrep A Ag FIA
STANDARD™ F Strep A Ag FIA
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

KIT CONTENTS



MATERIALS REQUIRED BUT NOT PROVIDED

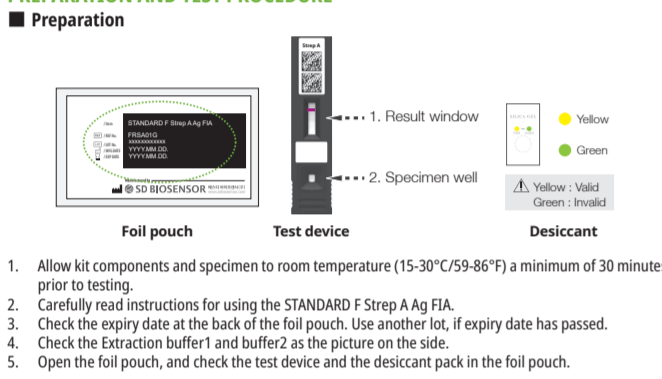
- STANDARD Analyzer
- Timer

SPECIMEN COLLECTION, PREPARATION AND STORAGE



- Throat swab
- Open the mouth widely.
- Depress the tongue with a tongue blade or spoon.
- Rub the swab on the back of the throat, both of the tonsils, the uvula and the posterior pharynx.
- Be careful not to touch the tongue, sides or top of the mouth with the swab.
- Swabs can 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.

PREPARATION AND TEST PROCEDURE



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

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

Positive/negative control processing

- Add 3 drops of extraction buffer 2 into the extraction buffer 1.



INTERPRETATION OF TEST RESULT

Result	COI (Cut-off index value)	Interpretation
Negative	COI < 1.0	Negative for Strep A Antigen
Equivalant	COI = 1.0-3.0	If COI value between 1.0-3.0, then bacterial culture test is recommended.
Positive	COI > 3.0	Positive for Strep A Antigen
Invalid	Not show the COI value	Retest should be performed.

The test result of a specimen is given either as Positive (+)Pos(+) or Negative (-)Neg(-) with a COI (Cut-off index) value. The COI is a numerical representation of the measured fluorescence signal.

Specimen processing

- Add 3 drops of extraction buffer 2 into the extraction buffer 1.

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 wounds. Most group A streptococcal infections are fairly mild, such as strep throat or impetigo. On rare occasions, these bacteria can cause invasive infection and even life-threatening disease when breaks in the skin or open sores 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 streptococcus include cellulitis and pneumonia. While 10%-15% of patients with invasive Group A streptococcus (GAS) die from the infection, approximately 25% of patients with necrotizing fasciitis and more than 30% with streptococcal toxic shock syndrome die. Thus, correct diagnosis and treatment are primarily of importance to the prevention of invasive disease caused by group A streptococcus. STANDARD F Strep A Ag FIA, employing immunofluorescent detection system with STANDARD F Analyzer, provides significantly fast, easy and accurate system to identify the target antigen from human throat swab. The test may aid in the reliable clinical diagnosis of group A streptococcal infection and enables supportive treatment decisions.

Intended use
STANDARD F Strep A Ag FIA is the fluorescence immunoassay to detect group A streptococcal (Strep A) antigen present in throat specimens from patients with clinical symptoms. This test is for professional diagnostic use and intended as an aid to early diagnosis of group A streptococcal infection. It provides only an initial screening test result. Specific alternative diagnosis methods should be performed in order to obtain the confirmation of group A streptococcal infection.

Test principle
STANDARD F Strep A Ag FIA is based on immunofluorescence technology with STANDARD F analyzer to detect group A streptococcal (Strep A) antigens. For extraction of the bacterial antigens, the patient's specimen is put into the extraction buffer containing mixed extraction buffer 1 and extraction buffer 2. After extraction, extracted specimen is applied into the specimen well of the test device and specimen migrates through the membrane from the specimen well. If Strep A antigen is present, it will be bound to by rabbit polyclonal anti-Strep A coupled to europium microparticle that migrates through the membrane of the test device. The fluorescent microparticle containing Strep A antigen will be captured by goat polyclonal anti-Strep A on the test line where it is detected by STANDARD F Analyzer. If Strep A antigen is not detected, 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 group A streptococcal (Strep A) antigen in the clinical specimen by processing the results using pre-programmed algorithms based on a pre-programmed algorithms and display the test result on the screen.

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

- Do not use the test kit.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not use extraction buffer 1 or extraction buffer 2 of another lot.
- Do not smoke, drink or eat while handling specimen.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
- Clean up spills thoroughly using an appropriate disinfectant.
- Handle all specimens as if they contain infectious agents.
- Observe all precautions against microbiological hazards throughout procedures.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

Analytical Sensitivity (Limit of Detection)

Strain	Limit of Detection (organisms/ml)
T1 (CNS1, SF 130)	3.38 x 10 ³
CNS5	5.69 x 10 ³

No	Microorganism/Virus	Concentration
1	Escherichia coli	2.0x10 ⁷ CFU/test
2	Parainfluenza virus 1	1.0x10 ⁷ TCID ₅₀ /test
3	Hemophilus influenzae	1.0x10 ⁷ CFU/test
4	Klebsiella pneumoniae	1.2x10 ⁷ CFU/test
5	Pseudomonas aeruginosa	1.5x10 ⁷ CFU/test
6	Staphylococcus aureus	2.0x10 ⁷ CFU/test
7	Staphylococcus epidermidis	5.0x10 ⁷ CFU/test
8	Streptococcus pneumoniae	1.0x10 ⁷ CFU/test
9	Cocciacellus A2	1.0x10 ⁷ TCID ₅₀ /test
10	Cocciacellus A3	1.0x10 ⁷ TCID ₅₀ /test

Cross Reactivity

STANDARD™ F Strep A Ag FIA does not be affected by those potential cross-reactive microorganisms and viruses below:

No	Microorganism/Virus	Concentration
11	Influenza A H1N1	2.0x10 ⁷ TCID ₅₀ /test
12	Parainfluenza virus 1	1.0x10 ⁷ TCID ₅₀ /test
13	Parainfluenza virus 2	1.0x10 ⁷ TCID ₅₀ /test
14	Adenovirus Type 1	1.0x10 ⁷ TCID ₅₀ /test
15	Adenovirus Type 2	1.0x10 ⁷ TCID ₅₀ /test
16	Adenovirus Type 5	2.0x10 ⁷ TCID ₅₀ /test
17	Adenovirus Type 11	2.0x10 ⁷ TCID ₅₀ /test

2. Cross Reactivity

STANDARD™ F Strep A Ag FIA does not be affected by those potential cross-reactive microorganisms and viruses below:

No	Microorganism/Virus	Concentration
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

3) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
10	oxymentazoline	0.01mg/mL
11	Phenylephrine	0.5mg/mL
12	Acetaminophen	5mg/mL
13	Halls honey lemon	25% v/v
14	Halls mentholylus	25% v/v

4) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

5) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

6) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

7) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
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6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

8) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
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5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

9) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

10) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

11) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

12) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

13) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

14) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

15) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

16) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

17) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances	Concentration of intergener
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/ml
6	Acetylsalicylic acid	20mg/ml
7	Guaiacol Glyceril Ether	20mg/ml
8	Whole blood	5% v/v
9	Budesonide	500mg/ml

18) Interference Substances

The following substances do not interfere the test result up to the indicated concentrations:

No	Potential interfering substances
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