Strep A Antigen
Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A rapid test for the qualitative detection of Strep A antigens in o*ropharyngeal* swab and nasopharyngeal(NP) swab specimens. For professional in vitro diagnostic use only.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION
1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE
The Strep A Antigen Rapid Test Cassette (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from nasopharyngeal(NP) swab and oropharyngeal swab specimens to aid in the diagnosis of Group A Streptococcal infection.

SUMMARY
Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.Left untreated,these infections can lead to serious complications,including rheumatic fever and peritonsillar abscess.Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.The Strep A Antigen Rapid Test Cassette (Colloidal Gold) is a rapid test to qualitatively detect the presence of Strep A antigens in *Oropharyngeal* swab and nasopharyngeal(NP) swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in *Oropharyngeal* swab and nasopharyngeal(NP) swab specimens.

TEST PRINCIPLE
The Strep A Antigen Rapid Test Cassette (Colloidal Gold) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in o*ropharyngeal* swab and nasopharyngeal(NP) swab specimens. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted o*ropharyngeal* swab and nasopharyngeal(NP) swab specimens reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials Provided
Test devices. Test panels are individually sealed in a foil pouch with a package of desiccant.
Extraction tube
Dropper tips
Extraction reagent 1 (2M NaNO2) Extraction reagent 2 (0.027M Citric acid)
Sterile swabs
Instruction for use.

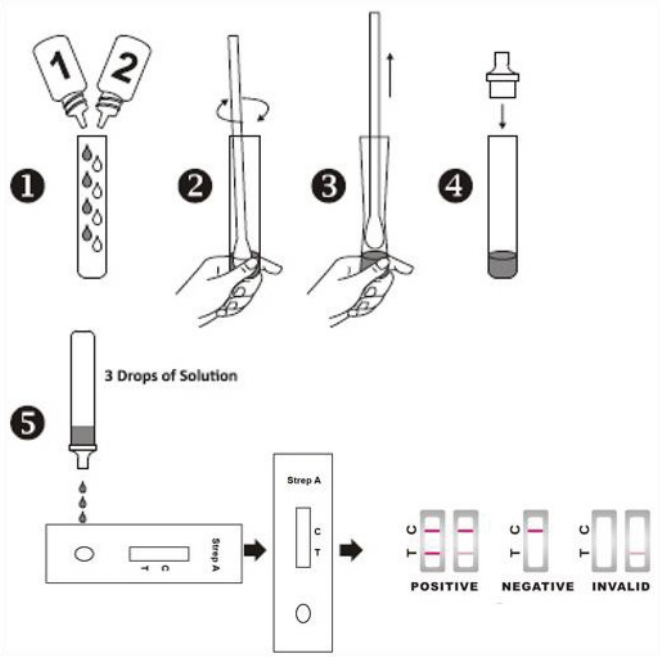
Materials Required But Not Provided
Timer

PRECAUTIONS
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used tests, specimens and potentially contaminated materials should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not use test if pouch is damaged.
8. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
9. The positive and negative controls contain sodium azide (NaN3) as a preservative.
10. Do not interchange reagent bottle caps.
11. Do not interchange external control solution bottle caps.

STORAGE AND STABILITY
Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. The shelf-life of the kit under these storage conditions is 24 months. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. Oropharyngeal swab specimen collection:Collect the oropharyngeal swab specimen with the sterile swab that is provided in the kit.Transport swabs containing modified Stuart's or Amie's medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
2. Nasopharyngeal swab specimen collection:Tilt patient's head back 70 degrees.Insert swab into nostril.(Swab should reach depth equal to distance from nostrils to outer opening of the ear.)Leave swab in place for several seconds to absorb secretions.Slowly remove swab while rotating it.
3. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
4. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Antigen Rapid Test Cassette (Colloidal Gold) .

ASSAY PROCEDURES
Allow the test, reagents, test specimen, and/or controls to reach room temperature (10-30℃) prior to testing.
1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Extraction Reagent 1 bottle vertically and add 4 full drops (approximately 240 µL) of Extraction Reagent 1 to an extraction tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. See illustration 1.
3. Immediately add the swab into the extraction tube, agitate the swab vigorously 15 times. Leave the swab in the extraction test tube for 1 minute. See illustration 2.
4. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. Add three drops of the solution (approx.120ul) to the sample well and then start the timer. Read the result at 5 minutes. Do not interpret the result after 10 minutes. See illustration 4 and illustration 5.



INTERPRETATION OF RESULTS
(Please refer to the illustration above)
Positive Result
Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A

positive result indicates that Strep A was detected in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Strep A present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

Negative Result

One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.

Invalid Result

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line 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

QUALITY CONTROL

1. Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms adequate membrane wicking.

2. External Quality Control

It is recommended that a positive and negative external control be run every 25 tests, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

3. Procedure for External Quality Control Testing

1) Add 4 full drops of Extraction Reagent 1 and 4 full drops of Extraction Reagent 2 into an extraction tube. Tap the bottom of the tube gently to mix the liquid.
2) Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3) Place a clean swab into this extraction tube and agitate the swab in the solution by rotating it at least 15 times. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4) Continue with Step 5 of Directions For Use.
5) If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS

1. The Strep A Antigen Rapid Test Cassette (Colloidal Gold) is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in o*ropharyngeal* swab and nasopharyngeal(NP) swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
3. A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in o*ropharyngeal* swab and nasopharyngeal(NP) swab specimens is not adequate or is below the detectable level of the test.
4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

EXPECTED VALUES

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta hemolytic Streptococcus. In school-aged children and adults, the incidence of Strep throat infection is about 40%.This disease usually occurs in the winter and early spring in temperate climates.

PERFORMANCE

1. **Sensitivity and Specificity**

The Strep A Rapid Test Cassette has been compared with another leading commercial rapid test using clinical specimens.

Method		Culture		Total Results
Strep A Antigen Rapid Test Cassette (Colloidal Gold)	Results	Positive	Negative	
	Positive	180	6	186
	Negative	9	301	310
Total Results		189	307	496

Relative Sensitivity: 95.2% (91.2%-97.8%)*
Relative Specificity: 98.0% (95.8%-99.3%)*
Accuracy: 97.0% (95.1%-98.3%)*
Confidence Intervals* 95%

Cross Reactivity

The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette. No mucoid-producing strains were tested.

Group B Streptococcus	Neisseria meningitidis	Serratia marcescens
Group F Streptococcus	Neisseria sicca	Klebsiella pneumoniae
Streptococcus pneumoniae	Branhamella catarrhalis	Bordetella pertussis
Streptococcus mutans	Group C Streptococcus	Neisseria gonorrhea
Staphylococcus aureus	Group G Streptococcus	Neisseria subflava
Corynebacterium diphtheria	Streptococcus sanguis	Hemophilus influenza
Candida albicans	Staphylococcus	Pseudomonas aeruginosa
Enterococcus faecalis	epidermidis	

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Code:GKPD030-1 Effective date: May 27, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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