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DIAQUICK Strep. A Cassette

(en) English

REF **Z98223CE**

Content

- 20 Cassettes individually packed (20 x REF Z98223B)
- 1x 10 mL Extraction Reagent A: 2.0 M $NaNO_2$
- 1x 10 mL Extraction Reagent B: 0.027 M Citric Acid
- 0.5 mL Positive Control: non-viable Strep. A; 0.01 % Proclin300
- 0.5 mL Negative Control: non-viable Strep. C; 0.01 % Proclin300
- 20 Extraction Tubes and Caps
- 20 Sterile Swabs
- 1 Workstation
- 1 Package Insert

For professional in vitro diagnostic use only.

INTENDED USE

The DIAQUICK Strep. A Cassette is a rapid chromatographic immunoassay for the qualitative detection of Strep. A antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

DIAGNOSTIC SIGNIFICANCE

Streptococcus pyogenes is a non-motile gram-positive coccus, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] 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.[3,4]
The DIAQUICK Strep. A Cassette is a rapid test to qualitatively detect the presence of Strep. A antigens in throat swab specimens at a cut-off concentration of 1.0 x 10^7 org/mL and providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep. A antigens in a throat swab specimen.

TEST PRINCIPLE

The DIAQUICK Strep. A Cassette is a qualitative, "lateral flow immunoassay" for the detection of Strep. A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep. A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen 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 generates a colored line in the test line region. The presence of this colored 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.

REAGENT COMPOSITION

The test contains Strep. A antibody coated particles and Strep. A antibodies coated on the membrane.

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

REAGENT PREPARATION

The test is ready to use.

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!
Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

- Reagent A:

H272: May intensify fire, oxidiser
H301: Toxic if swallowed.
H400: Very toxic to aquatic life.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not use test if pouch is damaged.
- Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- The positive and negative controls contain sodium azide (Proclin300) as a preservative.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

SPECIMEN COLLECTION AND STORAGE

- Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies 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.[5]
- 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.
- 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 DIAQUICK Strep. A Cassette.

TEST PROCEDURE

Allow the test, reagents, throat swab specimen, and/or controls to reach room temperature (15-30 ℃) 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.

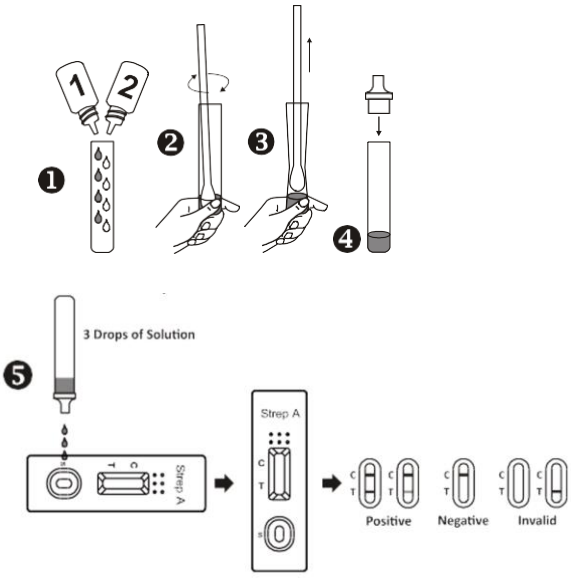
2. Hold the Extraction Reagent A bottle vertically and add 4 full drops (approximately 240 µL) of Extraction Reagent A to an extraction tube. Extraction Reagent A is red in color. Hold the Extraction Reagent B bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction Reagent B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent B to Extraction Reagent A 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. See illustration 4.

6. **Add three drops of the solution** (approx.100 µL) 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 5.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* 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: 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: 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 AND CALIBRATION

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 sufficient specimen volume, adequate membrane wicking and correct procedural technique.

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.

Procedure for External Quality Control Testing

1. Add 4 full drops of Extraction Reagent A and 4 full drops of Extraction Reagent B

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 squeeze 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. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Using three medical centers for evaluation, a total of 526 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by the DIAQUICK Strep. A Cassette. The plates were further streaked for isolation, and then incubated at 37 °C with 5-10 % CO_2 and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were sub-cultured and confirmed with a commercially available latex agglutination grouping kit. Of the 526 total specimens, 404 were confirmed to be negative and 122 were confirmed to be positive by culture. During this study, one Strep. F specimens yielded positive results with the Test. One of these specimens was re-cultured, then re-tested and yielded a negative result. Three additional different Strep. F strains were cultured and tested for cross-reactivity and also yielded negative results.

Method		Culture		Total Results
	Results	Positive	Negative	
DIAQUICK Strep. A Cassette	Positive	116	9	125
	Negative	6	395	401
Total Results		122	404	526

Relative Sensitivity: 95.1 % (95 %CI*: 89.6 %-98.2 %)
Relative Specificity: 97.8 % (95 %CI*: 95.8 %-99 %)
Accuracy: 97.1 % (95 %CI*: 95.3 %-98.4 %)
*95 % Confidence Interval

Positive Culture Classification	DIAQUICK Strep. A Cassette/Culture	% Agreement
Rare	8/10	80.0 %
1+	18/20	90.0 %
2+	19/20	95.0 %
3+	33/34	97.1 %
4+	38/38	100.0 %

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 DIAQUICK Strep. A 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 epidermidis	Pseudomonas aeruginosa
Enterococcus faecalis		

TRACEABILITY

The DIAQUICK Strep. A Cassette has been compared with a commercially available latex agglutination grouping kit which is the preferred reference method.

EXPECTED VALUES

Approximately 15 % of pharyngitis in children ages 3 months to 5 years is caused by Group A beta hemolytic Streptococcus.[6] In school-aged children and adults, the incidence of Strep throat infection is about 40 %.[7] This disease usually occurs in the winter and early spring in temperate climates.[3]

LIMITATIONS

1. The DIAQUICK Strep. A Cassette is for in vitro diagnostic use only. The test should be used for the detection of Strep. A antigen in throat 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 the throat swab 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.

WASTE MANAGEMENT

Please refer to the local legal requirements.

LITERATURE

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C., 1995,p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
5. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

USED SYMBOLS

Symbol	Description
Cont.	Content
	Do not reuse
	Do not use if package is damaged
CE	
IVD	
2°C 30°C	