PROCEDURE FOR EXTERNAL QUALITY CONTROL TESTING
1. Add 4 full drops of broth A and 4 full drops of broth B into an extraction test tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 2 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. Place a clean swab into the tube. Rotate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then 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.
4. Continue with Step 4 of Directions for Use.

LIMITATIONS
1. The Clearview® Strep A Exact II dipstick 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 qualitative nor the rate of increase in Strep A antigen concentration can be determined by this 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 obtained from this kit should be confirmed by culture. A negative result obtained from this kit should be confirmed by culture. A negative result obtained from this kit should be confirmed by culture. A negative result obtained from this kit should be confirmed by culture. A negative result obtained from this kit should be confirmed by culture. A negative result obtained from this kit should be confirmed by culture. A negative result obtained from this kit should be confirmed by culture.

4. 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. The incidence of Strep throat infection is about 40%. This disease usually occurs in the winter and early spring in temperate climates.

Performance Characteristics
Using three medical centers for evaluation, a total of 499 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 Clearview® Strep A Exact II dipstick. The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO₂ and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subcultured and confirmed with a commercially available latex agglutination grouping kit.

Rubber of the 499 total specimens, 375 were found to be negative by culture and 124 were found to be positive by culture. During this study, two 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 false-negative Strep F cultures were cultured and tested for cross-reactivity and also yielded negative results.

PERFORMANCE CHARACTERISTICS
The following organisms were tested at 1 to 4 dilutions per test and were all found to be negative when tested with the Clearview® Strep A Exact II dipstick. No mucoid-producing strains were tested.

SUMMARY
Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield Group A antigen that can cause serious infections such as pharyngitis, rheumatic fever, endocarditis, meningitis, puerperal sepsis, and arthritis. It cannot be retested, these infections can lead to serious complications, including hemolytic and post-streptococcal glomerulonephritis.

Sensitivity: 120/124 = 97% (91%-99%) Specificity: 355/375 = 95% (92%-97%) Accuracy: 475/499 = 95% (93%-97%)*

A Exact II dipstick. Personnel with various educational backgrounds performed the testing. Each physician’s office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results showed an 96% correlation with the expected results.

REFERENCES

CLIA: Yes

Made in China 05/16
1155873501

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San Diego CA 92121

Manufactured for Inverness Medical Professional Diagnostics

Clearview® is a registered trademark of the Inverness Medical family of companies.

PERFORMANCE CRITERIA
The Clearview Strep A Exact II dipstick is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen in throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

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**STORAGE AND STABILITY**

- The kit can be stored at room temperature or refrigerated (2-30°C). The test strip and the test kit must remain in the sealed pouch until use.
- Reagents are stable through the expiration date printed on the box. Do not use reagents beyond the expiration date.
- The positive and negative controls contain sodium azide (NaN₃) as a preservative.
- Do not interchange external control solution bottle caps.
- Do not interchange reagent bottle caps.
- Humidity and temperature can adversely affect results.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Wear personal protective equipment such as lab coats, gloves and goggles to prevent exposure of personnel.
- Different operators and methods can affect results.
- The kit can be stored at room temperature or refrigerated (2-30°C) prior to testing.
- Allow the test strip, reagents, and/or controls to reach room temperature (15-30°C) prior to testing.
- The test kit is not stable beyond its expiration date. Read the instruction manual for correct procedural technique. A clear background is an internal positive background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.
- Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample. Note: the intensity of the red color in the test line region (T) will vary depending on the concentration of Strep A present in the sample. Therefore, any shade of red in the test region (T) should be considered positive.
- One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). A negative result indicates that Strep A was not detected in the sample, or is present below the detectable level of the test. The patient’s sample should be cultured to confirm the absence of Strep A infection. Clinical symptoms are not consistent with results, obtain another sample for culture.

**QUALITY CONTROL**

**INternal QUALITY CONTROL**

- Internal procedural controls are included in the test. A line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**EXTERNAL QUALITY CONTROL**

- Quality control requirements must be performed in accordance with local, state, and federal regulations or accreditation requirements. Minimy, Inverness Medical Professional Diagnostics recommends that positive and negative external controls be run with each new lot and with each new untrained operator. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A streptococci ATCC reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

**INTERPRETATION OF RESULTS**

- The test strip contains a control region (C) and a test region (T). The control line(s) should always appear in the control region if the test has been performed properly. If a red control line does not appear, the test result is not valid.

- **Figure**: The illustration shows the interpretation of results. Each test strip contains a control region (C) and a test region (T). The control line(s) should always appear in the control region if the test has been performed properly. If a red control line does not appear, the test result is not valid.

**SPECIMEN COLLECTION AND PREPARATION**

- Only use reagents provided in the kit.
- Collect the throat swab specimens 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.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer
- 30 Sterile Swabs
- Reagent 1 (2M Sodium Nitrite)
- Reagent 2 (0.4M Acetic Acid)
- Negative control (Non-viable Strep C; 0.09% NaN₃)
- Positive control (Non-viable Strep A; 0.09% NaN₃)
- 5 Package insert
- 1 Workstation

**NOTE:** The kit does not contain a timer. Please use a timer in the laboratory to test this kit.

**DIRECTIONS FOR USE**

1. Remove the test strip from the sealed foil pouch and use it as soon as possible. First results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Reagent 1 bottle upright and add 4 full drops (approximately 240 µL) to an extraction test tube. Reagent 1 is red in color. Hold the Reagent 2 bottle upright and add 4 full drops (approximately 160 µL) to the tube. Reagent 2 is colorless. The addition of Reagent 2 to Reagent 1 changes the color of the solution from red to pale yellow. Top the bottom of the tube gently to mix the reagents.
3. Immediately add the throat swab into the tube of pale yellow solution. Rotate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then 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.
4. With arrows pointing down, place the test strip into the tube of solution and then start the timer. If the procedure is followed correctly, the liquid should be at or just below the maximum line (MAX) on the test strip. See the illustration below.
5. Leave the strip in the tube and read the result at 5 minutes. **Note:** After an extended period of time; therefore, do not read the result after 10 minutes.

**Figure**: The illustration shows the interpretation of results. Each test strip contains a control region (C) and a test region (T). The control line(s) should always appear in the control region if the test has been performed properly. If a red control line does not appear, the test result is not valid.

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