

Strep A Exact Dipstick

Dipstick is a rapid qualitative test for streptococcal antigen directly from

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Exact Dipstick is a rapid test for the detection of Group A Streptococcal antigen. This test is intended for use as an adjunct to confirm a diagnosis of Group A Streptococcal infection and is for laboratory use only.

INDICATION

Streptococcus is a major cause of infections such as tonsillitis, pharyngitis, sinusitis, and treatment of Group A Streptococcus has been shown to reduce the severity of complications, such as acute rheumatic fever and glomerulonephritis (ref.2).

Methods used for the detection of the disease and subsequent identification of the organism often require 24-48 hours. Rapid developments of immunological tests can detect Group A Streptococcal infection. Rapid swabs allow physicians to initiate therapy immediately.

Exact Dipstick utilizes a two-site technology for the detection of Group A Streptococcal antigen. The test consists of a membrane strip impregnated with rabbit anti-Strep A antibody and a nitrocellulose membrane. A gold conjugate antibody is formed at the end of the membrane.

Strep A antigen is extracted from the throat swab using the provided swabs. The test strip is then inserted into the sample. The mixture then moves across the membrane to the immobilized antibody at the test region. If Strep A antigen is present in the specimen, a colored sandwich of gold conjugate antibody is formed at the test region. The presence of this colored line at the test region is the result.

Strep A antigen, as the test strip is laterally across the membrane, a colored line at the test region appears. The presence of this colored line indicates a positive result. A sufficient volume of specimen must be obtained.

CONTENTS SUPPLIED

Each pack includes one test strip, one extraction tube, and one extraction tube. Swabs for throat swabs.

12ml): 5M Sodium Nitrite

12ml): 0.03M Citric Acid

- Positive Control (2 ml): Heat-killed Group A Streptococcus in solution (1 x 10⁸ organisms/ml) with 0.1 % sodium azide as a preservative.
- Negative Control (2 ml): Heat-killed Group B Streptococcus in solution (1 x 10⁸ organisms/ml) with 0.1 % sodium azide as a preservative.
- Two directional inserts: one waived and one moderately complex.
- One procedure card.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timing device.
- Alternate swabs (see specimen collection & handling).

STORAGE AND STABILITY

The Clearview Strep A Exact Dipstick should remain in sealed pouch and may be stored either refrigerated or at room temperature 2°-30°C (36°-86°F) until use or the expiration date printed on the kit box.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only.
- Do not use after stated expiration date on the kit box.
- Do not reuse the test.
- Discard the test strip if package is torn, ripped or if strip itself is damaged.
- Do not mix reagent or control bottle caps.
- Do not mix reagents from different lots.
- To obtain accurate results, package insert instructions must be followed.
- Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All contaminated waste such as swabs and Clearview Strep A Exact Dipstick strips should be properly disposed.
- Extraction Reagents 1 and 2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.



Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions, always flush with copious amounts of water to prevent azide build-up.

SPECIMEN COLLECTION AND HANDLING

Follow standard clinical methods described by Facklam (ref.2) and Ross (ref.6). Use only polyester tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped or wooden shafted swabs. To collect throat specimens, hold down the tongue with a depressor and rub the swab on the tonsils, or any areas of inflammation with the signs of pus or redness in the back of the throat. Avoid contact with the tongue or sides of the mouth with the swab.

It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately they should be placed into a dry, sterile and tightly sealed plastic tube for storage. Swab specimens can be stored at room temperature 20°-30°C (68°-86°F) for up to 4 hours or refrigerated 2°-8°C (36°-46°F) for up to 24 hours.

If a liquid transport method is employed, use Liquid Stuart's Transport Media or Liquid Amies Transport Media as outlined in the manufacturer's instructions. Do not use charcoal or agar transport media.

If a bacteria culture is desired, gently streak the swab on a 5% sheep blood agar plate before using it in the Clearview Strep A Exact Dipstick. The Extraction Reagents kill the bacteria on the swab and makes it impossible to culture. Alternatively, a dual swab procedure or a subsequent second swab specimen may be collected for the culture. If a second swab sample is collected, rub the swab ends together to ensure even distribution of bacteria before performing the Clearview Strep A Exact Dipstick test and the bacteria culture.

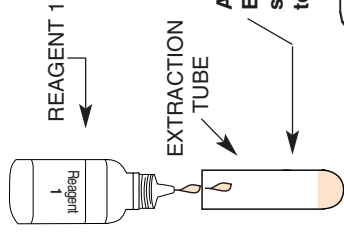
TEST PROCEDURE

- Review "specimen collection" instructions. Bring the test strips and reagents to room temperature prior to testing. Do not open test packs until ready to perform the assay to avoid condensation of moisture on the membrane.
- To avoid cross contamination, do not allow the tip of the reagent bottles to come in contact with throat swabs or Extraction Tubes.
- Shake the Extraction Reagent and Control bottles before use.

1. Open the test package and place the Extraction Tube in the designated area of the plastic workstation. Add 3 drops of Extraction Reagent 1 to the Extraction Tube. The solution should be purple to pink in color.
2. Add 3 drops of Extraction Reagent 2 to the Extraction Tube. The solution must turn yellow in color.
3. Place the throat swab specimen in the Extraction Tube. Rotate the swab inside the tube using a circular motion to roll the side of the Extraction Tube so that liquid is expressed and reabsorbed from the swab. Let stand for a minimum of 1 minute. You may leave the Extraction Tube for 15 minutes at room temperature.
4. Gently squeeze the swab firmly against the Extraction Tube to expel as much liquid as possible from the swab. Discard the swab.
5. Immerse the test strip into the Extraction Tube with the arrows pointing toward the extracted sample solution. Leave the test strip in the Extraction Tube. Start the timing device.
6. Read results in 5 minutes. Depending on the number of organisms on the swab, positive results may be visible as soon as 1 minute. However, to confirm a negative result the complete reaction time of 5 minutes is required. Do not read results after 10 minutes.

HOW TO PERFORM TEST

1

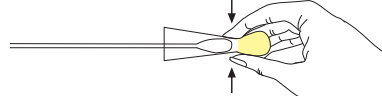


2



2. The solution must turn yellow.

4



Squeeze the tube firmly against swab to expel as much liquid as possible.

5 minutes



Immerse the test strip in the Extraction Tube. Start the timing device.

12ml): 5M Sodium Nitrite

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