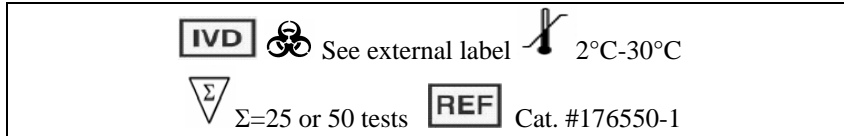




CORTEZ DIAGNOSTICS, INC.

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For Self Testing

OneStep Strep A InstaTest

FOR THE QUALITATIVE ASSESSMENT OF STREPTOCOCCAL GROUP A
 ANTIGEN FROM THROAT SWABS OR CONFIRMATION FROM CULTURE
 PLATES

For in vitro Diagnostic Use

INTENDED USE

Cortez Diagnostics, Inc. Strep A test is a qualitative test that detects group A streptococcal antigen. The test is a rapid, in vitro assay. It is intended for professional use to help diagnose Strep A infection in hospital and clinical laboratories.

EXPLANATION OF THE TEST

Beta-hemolytic group A streptococcus is the most common cause of upper respiratory infection in human. The most commonly occurring disease is pharyngitis. The highest morbidity is usually found in children. The infection can lead to serious complication, including rheumatic fever and acute glomerulonephritis. Rapid diagnosis and appropriate antibiotic therapy appear to be the best means of preventing these complications. The traditional means of detecting group A streptococcal infection involves 24-48 hour culture of throat swab specimens or other exudates, confirming beta-hemolysis, and showing susceptibility to bacitracin. This long process of diagnosis often causes physicians to administer therapy without first knowing the etiologic agent involved.

Cortez Diagnostics, Inc. Strep A test detects group A streptococcus by immunological means. It utilizes the antibodies that recognize the specific antigens from cell walls of the group A streptococcus. The test result can be obtained within 10 minutes.

TEST PRINCIPLE

Cortez Diagnostics, Inc. Strep A test is a sandwich immunoassay. The carbohydrate antigen of group A streptococcus is extracted by chemical extraction first. The extracted antigen then is transferred to sample pad, it moves through the conjugate pad and mobilizes gold anti-Strep A polyclonal antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-Strep A polyclonal antibody that is coated on the test region. If Strep A antigen is present, the result is

the formation of a colored band in the test region. If Strep A antigen is lower than detection level in the sample, the area will remain colorless. The sample continues to move to the control area where Goat anti-rabbit IgG antibody will capture gold-antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

MATERIAL PROVIDED

1. Cortez Diagnostics, Inc. Strep A Test device
2. Extraction Reagent 1 (2 M Sodium Nitrite)
3. Extraction Reagent 2 (1 M Acetic Acid)
4. Individually packaged sterile rayon-tipped swabs or solid shafts (optional).

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Test tube or other appropriate extraction sample collectors.
2. Appropriate throat swab for specimen collection
3. Timer or clock

STORAGE

Store the test device at 2 to 30°C. Do Not Freeze.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

SPECIMEN COLLECTION

1. Collect throat swab specimens by standard clinical methods using the sterile swabs. Do not use swabs with cotton or calcium alginate tips or wooden shafts.
2. Do not use swabs impregnated with charcoal or transport media containing agar gelatin.
3. It is recommended that swab specimens be processed as soon as possible after collection. If immediate testing is not possible, the samples should be placed in a dry test tube and covered. The samples can be refrigerated at 2 – 8°C for up to 5 days.

QUALITY CONTROL

1. Good laboratory practice recommends the use of external controls to assure that the reagents and assay procedure are performing properly. Controls are available from commercial vendors.
2. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

PROCEDURE

A. Extraction

1. Add 5 drops of extraction reagent 1 and extraction reagent 2 respectively to a clean test tube.
2. Place the specimen swab in the tube, incubate at room temperature for 2 minutes.
3. Remove as much extract from the swab as possible by pressing and rotating the fiber portion against the wall of test tube.
4. Discard the swab. The extraction mixture can be tested immediately or at any time within the following 60 minutes.

B. Test Procedure

1. Remove the test device from the sealed foil pouch.
2. Withdraw the sample with a transfer pipette or a pipetter.
3. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 µl) of sample into the sample well.
4. Read the result at 8 minutes.

Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Positive:

If two colored bands are visible within 3 minutes, the test result is positive and valid.

Negative:

If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid result:

The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

LIMITATIONS OF THE PROCEDURE

1. Respiratory infections, including pharyngitis, can be caused by organisms other than group A streptococcus.
2. The test will not differentiate asymptomatic carriers from those exhibiting infection.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Group A streptococcus is responsible for approximately 19% of all upper respiratory tract infection. Streptococcal pharyngitis is seasonal in nature with the highest prevalence found during the winter and early spring. Males and females are equally affected.

PERFORMANCE CHARACTERISTICS**Sensitivity:**

The sensitivity of Cortez Diagnostics, Inc. Strep A is 1×10^2 CFU/test (CFU: clone forming unit).

Specificity:

The following organisms at 1×10^7 organisms/test yielded negative results:

Group B Streptococcus
Group C Streptococcus
Group D Streptococcus
Group F Streptococcus
Group G Streptococcus
Staphylococcus aureus
Staphylococcus epidemidis
Pseudomonas aeruginosa
Klebsiella pneumoniae
Neisseria gonorrhoeae

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