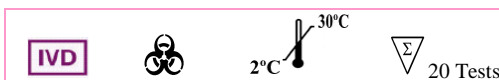




OneStep Strep A RapiCard™ InstaTest

Cat#176550-20-21



INTENDED USE

Cortez Diagnostics, Inc. OneStep Strep A RapiCard™ InstaTest is a qualitative 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.

SUMMARY AND EXPLANATION

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.

Strep A RapiCard™ 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 OneStep Strep A RapiCard™ 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 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.

SPECIMEN COLLECTION AND PREPARATION

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.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. OneStep Strep A RapiCard™ InstaTest 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 provided

1. Test tube or other appropriate extraction samples collectors

2. Appropriate throat swab for specimen collection
3. Timer or clock

ASSAY PROCEDURE

A. Extraction

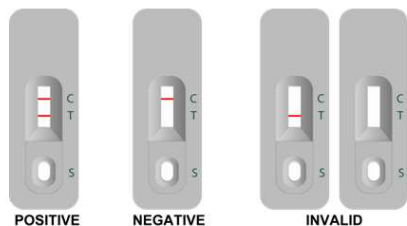
1. Add 5 drops of extraction reagent 1 and extraction reagent 2 respectively to a clean test tube.
2. Place the specimen swab in the tube, incubate at room temperature for 2 minutes.
3. Remove as much extract from the swab as possible by pressing and rotating the fiber portion against the wall of test 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 results between 8 and 10 minutes after adding the samples.

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 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.

PRECAUTIONS


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


STORAGE

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

REFERENCES

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ISO 13485
ISO 9001



**Diagnostic Automation/
 Cortez Diagnostics, Inc.**
 23961 Craftsman Road, Suite E/F,
 Calabasas, California 91302 USA

Date Adopted	Cat # 176550-20-21		
2009-11-01	CORTEZ - OneStep Strep A RapiCard™ InstaTest-2014		
<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">EC</td> <td style="padding: 2px;">REP</td> </tr> </table>	EC	REP	CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands. www.cepartner4u.eu
EC	REP		
Revision C Date:01-14-2015			

QUALITY CONTROL

1. Good laboratory practice recommends the use of external controls to assure that the reagents and assay procedures 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.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity of Cortez Diagnostics, Inc. OneStep Strep A RapiCard™ InstaTest is 1x 10⁵ CFU/test (CFU: clone forming unit).

Specificity:

The following organisms at 1 x 10⁷ 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