

In vitro Diagnostics
INTENDED USE

Sensit STREP A Rapid Test Kit is a qualitative immunochromatographic assay for the detection of Streptococcal antigen from patient throat swab specimens.

SUMMARY & TEST DESCRIPTION

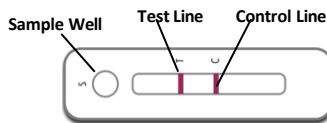
Streptococci are a genus of gram-positive, spherical bacteria that appear in chains. There are over 30 recognized species within this genus. Streptococci cause an array of diseases in humans including pharyngitis, scarlet fever, impetigo, rheumatic fever, pneumonia, meningitis, otitis media, sinusitis, endometritis, and septicemia.

Streptococcal pharyngitis, or "strep throat," is a common bacterial infection found in childhood. Group A Streptococci (GAS) are responsible for the most streptococcal pharyngitis cases although other groups, such as C and G, may also cause disease. Strep throat affects all age groups but is most common in children between the ages of 5 to 15 years of age. Strep throat has an incubation period of 2-4 days. Classic symptoms include the abrupt onset of sore throat accompanied by fever, malaise and headache. Children may experience additional symptoms such as nausea, vomiting and abdominal pain. Physical findings often reveal pharyngeal erythema, enlarged tonsils with exudate and tender cervical lymphadenopathy. Viral pharyngitis may mimic streptococcal pharyngitis, but unlike strep throat, viral pharyngitis will often be accompanied by cough and rhinorrhea and cervical lymphadenopathy and pharyngeal exudates are usually absent in viral pharyngitis. The common cold, influenza, adenovirus and mononucleosis may also present with signs and symptoms pharyngitis.

Sensit STREP A Rapid Test utilizes Antibody against Streptococcus antigen as the capture molecule. Colloidal gold conjugated Antibody against Streptococcus antigen is used as the detection antibody.

TEST PRINCIPLE

Sensit STREP A Rapid Test works on chromatographic immunoassay. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T: Anti-Streptococcus and C: Goat Anti Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where Streptococcal antigen present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized antibodies (on test line) producing a visible line on the membrane. If the respective antigen is not present in the sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
 - a. Onetest card
 - b. Dessicant
2. Assay Diluent- In dropper bottle
3. Swab
4. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

- Collect the secretion from throat and tonsils of symptomatic patients using the swab provided
- Collect 10 drops of assay buffer in an eppendorf. Insert swab into assay diluent and agitate it sufficiently in order to ensure good sample extraction.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

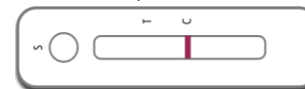
1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 4 drops of the extracted sample (Prepared as mentioned above) in the sample well of the test device (shown by arrow). Do not add particulate matter with the liquid.
3. Wait 10 minutes, read and interpret the results. The result is considered invalid after 15 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

Positive: Color bands at position C and T.



Negative: Color band at position C.



Invalid: Color band at C does not appear



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