



berkeleyhealth STREP A

Self-test for the detection of group A β -hemolytic Streptococcus in throat swab



STREPTOCOCCUS A

Group A β -hemolytic Streptococcus (also known as Streptococcus pyogenes) infection of the throat is one of the most common bacterial cause of acute pharyngitis and is also responsible for some skin infections such as impetigo and erysipelas. Most sore throats are caused by viral infections which clear up on their own without antibiotic treatment, which would be useless. While Strep A throat infections sometimes can go away within a few days without treatment, physicians prescribe antibiotics to prevent related complications that can be serious, such as rheumatic fever or acute glomerulonephritis.

WHO ARE THE INTENDED USERS

STREP A TEST can be carried out if there are symptoms such as pain when swallowing, sore throat, red and swollen tonsils, small red patches on the back of the palate, swollen lymph nodes, fever, headache, nausea or vomiting, especially in children.

WHY - BENEFITS

STREP A TEST helps to quickly know whether a sore throat is caused by the bacterium Streptococcus A, which generally requires an antibiotic treatment, or other germs (usually viruses) that do not require this type of treatment.

TEST PRINCIPLE

STREP A TEST is an immunochromatographic test that detects the presence of specific Streptococcus A antigens in throat swab samples by using special monoclonal antibodies..

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 ⁴ CFU/mL	94.29%	100%	97.14%

Performance data obtained by clinical study with 70 samples tested comparing STREP A Test with another rapid immunochromatographic test used as reference method.

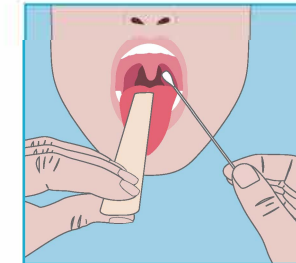
CONTENT:

1 hermetically sealed protective aluminium pouche containing: 1 test device and a desiccant bag; 1 sterile swab; 1 sterile wooden tongue depressor; 1 empty plastic test tube for sampling, with dropper; 1 vial with dropper containing the STREP A TEST - R1 solution required for 1 test (blue cap); 1 vial with dropper containing the STREP A TEST - R2 solution required for 1 test (green cap); 1 workstation and 1 instructions for use leaflet.

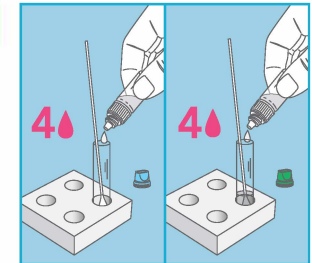
CLINICAL EVIDENCES

1. Banerjee S, Ford C. "Rapid Tests for the Diagnosis of Group A Streptococcal Infection: A Review of Diagnostic Test Accuracy, Clinical Utility, Safety, and Cost-Effectiveness". Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2018 May. CADTH Rapid Response Reports.
2. Centers for Disease Control and Prevention. Adult appropriate antibiotic use summary. <http://www.cdc.gov/getsmart/community/materials-references/print-materials/hcp/adult-approp-summary.pdf> 2016.
3. Ulor C., Bjerrum L., Munck A., Cots JM., Hernández S., Moragas A.; HAPPY AUDIT Investigators. "Access to point-of-care tests reduces the prescription of antibiotics among antibiotic-requesting subjects with respiratory tract infections." *Respir Care*. 2014 Dec.

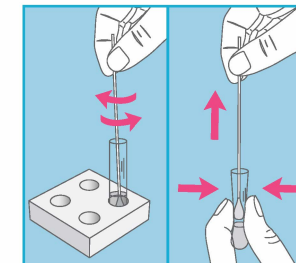
HOW TO USE IT



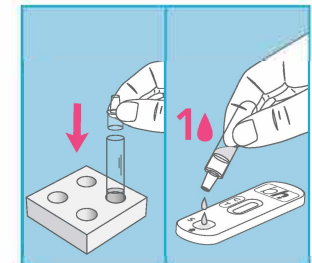
1) Collect a throat sample using the supplied swab and the tongue depressor



2) Insert the absorbent cotton tip of the swab into the extraction tube placed on the workstation and add the two diluent Solutions.



3) Mix the solutions and leave the swab inside the tube for 2-5 minutes. Then remove it and squeeze the cotton tip to collect as much liquid as possible.



4) Apply the dropper to the tube and dispense 1 drop into the well.