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Strep A Self-Test

A rapid throat swab self-test to detect strep A, a bacterial throat infection that requires treatment with antibiotics.

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Instructions for use

Streptococcus A, commonly known as 'strep A'

Group A β -hemolytic streptococcus (also known as *streptococcus pyogenes*) is a Gram-positive bacterium that causes a variety of pathological conditions and complications, including pharyngitis (throat infections), skin infections (such as impetigo and erysipelas), acute glomerulonephritis, sepsis and rheumatic heart disease. Pharyngitis is commonly caused by viral infections and less often by bacterial infections, which require treatment with antibiotics. The Strep A Self-Test is an immunological test designed to identify group A beta-hemolytic Streptococcus using a throat swab. It helps to understand quickly if a sore throat is caused by streptococcus A (strep A) bacteria in pharyngeal infections or by other microorganism that do not require treatment with antibiotics.

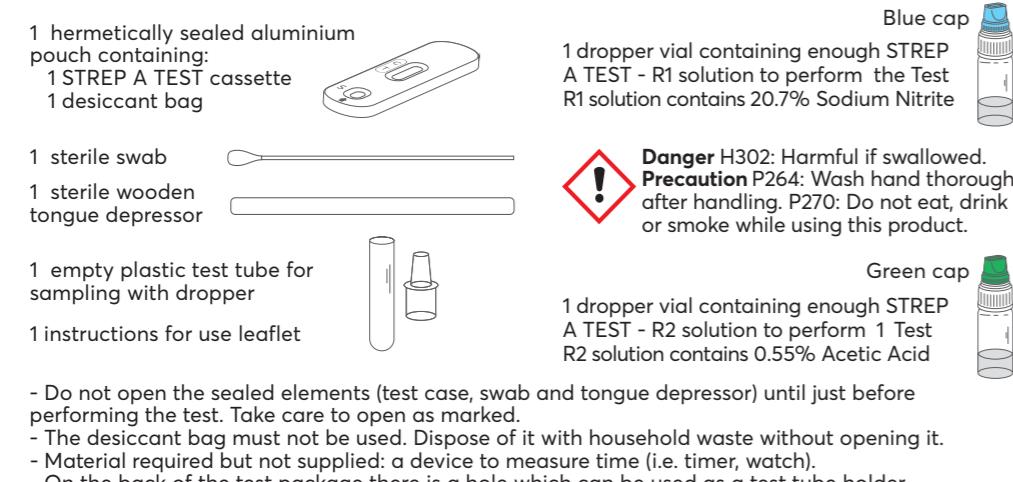
Principle of the test

The Strep A Self-Test is an immunochromatographic test that detects the presence of streptococcus A (strep A) specific antigens, using gold-conjugated antibodies integrated into the reactive strip.

References

- 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.
- 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.
- Llor 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.

Content



Precautions

- Read these instructions for use carefully before performing the test. The test is reliable if the instructions are followed correctly (reaction times, how the sample is collected and the extraction instructions shown).
- Keep the test out of the reach of children.
- Not suitable for use on children under the age of 2 years.
- Do not use the test after the expiry date or if the package has been damaged.
- Store the test components at a temperature between +4 °C and +30 °C. Do not freeze.
- Use individual tests once only.
- In vitro diagnostic device for individual use.
- The test is for external use only. Do not swallow solutions 1 and 2 and the other items in the box! If swallowed, seek medical advice immediately. Show the remaining parts of the box, the instructions for use and the package.
- If liquids come into contact with the eyes, skin or other mucosae, rinse immediately and thoroughly with water and contact a physician. Show the vials' labels.
- After using, dispose of all components according to local laws. Liquid wastes should not be disposed of down the drain.
- Do not open the sealed elements (test case, swab and tongue depressor) until just before performing the test. Take care to open as marked.
- The desiccant bag must not be used. Dispose of it with household waste without opening it.
- Material required but not supplied: a device to measure time (i.e. timer, watch).
- On the back of the test package there is a hole which can be used as a test tube holder.

F.A.Q. – Questions and answers

How does the Strep A Self-test work? Group A β -hemolytic streptococcus could be involved in infections of the pharynx. For appropriate antibiotic treatment to be administered, the bacterium must be identified first. The Strep A Self-Test can detect streptococcus A (strep A) antigens through the specific antibodies it contains.

When can the test be used? The Strep A Self-Test can be carried out if there are symptoms such as pain when swallowing, sore throat, red and swollen tonsils (sometimes with white spots or pus), small red patches on the back of the palate (soft or hard), swollen lymph nodes, fever, headache, nausea or vomiting, especially in children.

Can the result be incorrect? The result is correct if the instructions are followed carefully. However, the result may be incorrect if the Strep A Self-Test is wet before performing the test or if the sample from the pharynx is not collected and prepared correctly (carefully follow the instructions for collecting the sample from the pharynx –fig.D). Incorrect results may also be obtained if the test is carried out after treatment with antibiotics or at the beginning of the infection (the concentration of bacteria is below the level of detection).

How do I interpret the test if the colour and intensity of the test and control bands are different? The colour and the intensity of the bands are not important for the interpretation of the result. The bands must be complete and equal in size. The test is positive regardless of the intensity of the colour of the Test band, even if it is weak.

What is the purpose of the control band? The appearance of this band means the test has worked correctly.

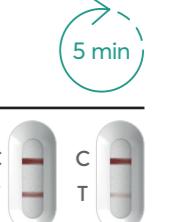
What should I do if the result is positive? If the result is positive, streptococcus A (strep A) has been detected in the sample from the pharynx and you must consult a physician. Please be aware the Strep A Self-Test cannot distinguish between live and dead bacteria. Patients who have recently recovered

- At the end of the incubation period, remove the test tube (with the swab and extraction fluid still in it) from the tube holder in the box. Using your thumb and index finger, press the sides of the test tube to release as much fluid as possible from the swab's cotton tip and collect it in the test tube. Dispose of the swab in compliance with local laws and put the test tube back into the tube holder in the box. **FIG. I**
- Add the supplied dropper to the plastic test tube. **FIG. L**
- Dispense 1 drop into the well in the test case. **FIG. M**
Note: If the dispensed drop contains air bubbles, add another drop to the well.
- Read the results after 5 minutes (some positive results can be seen after just 1 minute). Do not read after 10 minutes.

Results interpretation

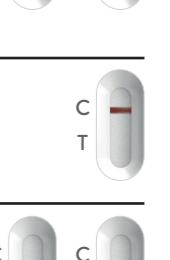
Read the result after 5 minutes. Do not read the result after 10 minutes.

Positive result · Two coloured bands appear in the reading window by the T (test) and C (control) signs. The T band may be less intense (lighter) than the C line.



This result means that the test has detected the presence of streptococcus A specific antigens in the sample and you likely have a strep A infection. You should consult a physician.

Negative Result · A coloured band appears only under the C (control) sign. **This result is negative and means that streptococcus A antigens have not been detected in the sample from the pharynx or that their amount is too low to be detected therefore a strep A infection has not been detected.**



Non valid result · No bands appear or there is a line only under the T (test) sign and not under the C (control) sign. In this case it is not possible to interpret the result of the test, which must be considered not valid. Repeat using a new test.



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INTERNAL CHANGE ID	SQH905-0				

Medical devices inside the kit

STERILE | R
Sterile swab

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STERILE | EO
Sterile tongue depressor

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Sterile tongue depressor

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