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## newfoundland Strep A Self-Test

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

newfoundland.io Instructions for use

Medical devices inside the kit

STERILE R

Coplan Italia SpA  
Via F.Perotti 10  
25125 Brescia  
0123 Italy

STERILE EO

Applimed SA  
Zi, Route de Pra de Plan 1,  
CH-1618 Châtel-Saint-Denis - Switzerland  
1639

STERILE EO

Jiangsu Suyun Medical Materials Co., Ltd  
No.18 Jin Qiao Road Dapu Industrial Park  
222002 Lianyungang Jiangsu Province  
0123 People's Republic of China

EC REP

Dansu A/S  
Sandbakken 1-3, Gørlose  
DK-3660 Stenløse - Denmark

EC REP

Shanghai International Trading Corp. GmbH  
(Europe)  
Elffestrasse, 80, D-20537  
Hamburg - Germany

### Streptococcus A, commonly known as 'strep A'

Group A  $\beta$ -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 designated 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.

### F.A.Q. – Questions and answers

**How does the Strep A Self-test work?** Group A  $\beta$ -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

from Streptococcus A (strep A) or similar infections may test positive because of inactive bacteria that are still present in the body.

**What should I do if the result is negative?** A negative result means that the symptoms were not caused by the streptococcus A (strep A) or that the sample did not contain a concentration of bacteria that was high enough to be detected by the test. If symptoms persist, seek medical advice.

**Is the result reliable if read after 10 minutes?** No. The test must be read 5 minutes after the procedure is completed and no later than 10 minutes from this time.

**How accurate is the Strep A Self-Test?** The device specifically identifies Group A  $\beta$ -hemolytic Streptococcus when its concentration in the extracted sample is equal to or higher than  $10^4$  CFU/mL (cut-off value). In some cases, samples with concentrations below this value (down to  $5 \times 10^3$  CFU/mL) can yield a positive result. The test is very accurate. Assessment reports show an analytical specificity of 99,00% (CI 95%: 97,63 – 100%) and a sensitivity of 91,89% (CI 95%: 78,70 – 97,20%) with an overall concordance rate of 97,90% (CI 95%: 96,08 – 99,72%). Although this test is reliable, it may yield false positive and negative results.

### Symbols

IVD

In vitro diagnostic device

Read the instructions before use

STERILE R

Sterilised using irradiation

STERILE EO

Sterilised using ethylene oxide

EC REP

Authorised Representative in the European Community

Temperature limits

Do not reuse

Sufficient for <n> tests

Expiry date (last day of the month)

List number

Lot number

CE marking

Legal manufacturer

### Content

1 hermetically sealed aluminium pouch containing:  
1 STREP A TEST cassette  
1 desiccant bag

1 sterile swab

1 sterile wooden tongue depressor

1 empty plastic test tube for sampling with dropper

1 instructions for use leaflet

Blue cap

1 dropper vial containing enough STREP A TEST - R1 solution to perform the Test  
R1 solution contains 20.7% Sodium Nitrite

Danger H302: Harmful if swallowed.  
Precaution P264: Wash hand thoroughly after handling. P270: Do not eat, drink or smoke while using this product.

Green cap

1 dropper vial containing enough STREP A TEST - R2 solution to perform 1 Test  
R2 solution contains 0.55% Acetic Acid

- 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.

### 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.
- Do not switch the caps of the reagent vials.
- All kit components are single-use, with the exception of the test package (which can be re-used as test tube holder) instructions for use and solution 1 and 2, which must be stored, closed with their caps, at a temperature between +4°C and +30°C.

### Test procedure

- Wash your hands with warm water and soap, rinse with clean water and dry.
- Place the empty plastic test tube in the tube holder in the box. –FIG. A
- Collecting the sample:
  - Open the package containing the tongue depressor, leaving it inside the package and next to you.
  - Open the package containing the sterile swab. **Avoid touching the cotton tip** and remove the swab using the plastic handle. –FIG. B
  - Stand in front of a mirror, tilt your head backwards and open your mouth as wide as possible.
  - Pick up the tongue depressor with one hand and flatten the tongue.
  - Use the other hand to place the swab close to the throat. Touch the back of the throat - the area around the tonsils 3 and any reddened or painful part (soft palate 1, uvula 2) with the cotton tip –FIG. C. **Rotating** the swab is recommended because it increases the amount of collected sample. **If you are struggling, ask someone to help you collect the sample.** –FIG. D
- After collecting sample, insert the swab's cotton tip into the supplied plastic test tube, that you had previously placed in the tube stand in the box. –FIG. E
- Open the vial STREP A TEST - R1 by **unscrewing only the blue cap** (leave the white part firmly sealed), then add **4 drops** into the test tube and close it with the cap. –FIG. F
- Next, open the vial STREP A TEST - R2 by **unscrewing only the green cap** (leave the white part firmly sealed), then add **4 drops** into the test tube and close it with the cap. –FIG. G **WARNING: the addition of R2 to R1 leads to the formation of a solution for which the indications described in point 8 and 9 of the "precautions" apply.**
- Holding the swab's plastic handle, rotate the swab against the sides of the test tube about 10 times to thoroughly mix the solution. Leave the swab to incubate for 2-5 minutes. –FIG. H

- 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. Remove the swab. –FIG. I  
Dispose of the swab in compliance with local laws and put the test tube back into the tube holder in the box.
- 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.

C  
T

C  
T

C  
T

C  
T

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