Your partner for rapid testing

PRIMA Lab SA
Via Antonio Monti 7
CH-6828 Balerna - SWITZERLAND
+41 91 605 1030
primalabsa.ch

EC REP Qarad EC-REP BV
Pas 257, 2440 Geel
Belgium

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STREP A RAPID TEST

Rapid Test for the detection of group A ß-hemolytic Streptococcus in throat swab

INSTRUCTIONS FOR USE

5 min. 20 tests

CE

STREPTOCOCCUS A

Throat infection with *group A ß-hemolytic Streptococcus* (also known as *Streptococcus pyogenes*) is the most frequent bacterial cause of acute pharyngitis and it is also responsible for some skin infections such as impetigo and erysipelas. Most sore throats, on the other hand, are caused by viral infections, which are cured without the need of antibiotic treatments, which would therefore be useless. *Streptococcus A* infections can resolve in a few days without treatment, although doctors generally prefer to prescribe antibiotics to prevent infection-related complications that can also be serious, such as rheumatic fever or acute glomerulonephritis. *Group A Streptococci* continue to be a focus of interest not only because of their causal role in acute streptococcal pharyngitis and other pyogenic infections but also because of their association with poststreptococcal sequelae, specifically, acute rheumatic fever and acute glomerulonephritis. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathological agent.
For the screening of *Group A Streptococcus* infection several methods are currently used including the susceptibility of the organism to a bacitracin disc placed on a sheep blood agar plate, latex agglutination and enzyme immunoassay.
STREP A RAPID TEST is a rapid immunological test for the qualitative and visual detection of *group A Streptococcus* bacteria in throat infections. The test helps to quickly identify whether a sore throat is caused by Strep A rather than by other pathogens (usually viruses) that may not require antibiotic treatment.

PRINCIPLE OF THE TEST

STREP A Rapid Test detects specific *Streptococcus A* antigens thanks to special polyclonal gold conjugate antibodies embedded to a test strip. The specimen, which is throat swab, is taken with a disposable sterile rayon swab. The specimen is placed in a plastic collection tube where the user dispenses a specific volume of 2 extraction reagents (in order to extract specific Strep A-group antigens). After an incubation time, the obtained sample-solution is dispensed onto the test-cassette (sample well).
The provided reagents are:
- R1: solution mainly containing Sodium Nitrite and Phenol Red.
- R2: solution mainly containing Acetic Acid.
Once mixed, the two solutions create Nitrous Acid, acting as Strep A-group specific antigen extractor.
In case of a Strep A concentration equal or higher than 10^4 CFU/mL in the patient's sample, the specific antigens present in the sample solution are firstly bound by the anti-Strep A polyclonal antibodies labelled with gold molecules. The immunocomplexes are selectively captured by the test line (T line, made of purified anti-Strep A polyclonal antibodies), thus showing a red–purple band appearance in correspondence of the T line, pointing out a positive result. In case of absence of Strep A or when its levels in patient's sample are lower than the cut-off value (10^4 CFU/mL), not enough specific immunocomplex is formed. Consequently, only one band, the C line, is visible indicating a negative result.
To serve as a procedural control, a colored line will always appear in the Control line region, indicating that the test procedure has been properly performed and that the test components and reagents have operated as intended.

REFERENCES

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CONTENT

THE PACKAGE CONTAINS:

- 20 hermetically sealed aluminum pouches each containing:
  1 STREP A TEST cassette and 1 desiccant bag;
- 20 sterile swabs;
- 20 sterile wooden tongue depressors;
- 1 workstation;
- 20 empty plastic extraction tubes with dropper
- 1 dropper vial containing enough STREP A TEST-R1 solution to perfrom 20 tests
  R1 contains 20.7% Sodium Nitrite
  H302: Harmful in case of ingestion
  P264: Wash carefully your hands after use
  P270: Do not eat, drink or smoke while using this product.
- 1 dopper vial containing enough STREP A TEST- R2 solution to perform 20 tests
  R2 contains 0.55% Acetic Acid
- 1 Instructions for use leaflet

- Required material not supplied: a timer (e.g. timer, watch).

- 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 dessiccant bag must not be used. Dispose it with household waste without opening it.

PRECAUTIONS

1. 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).
2. Keep the Test out of the reach of children.
3. Not suitable for use on children under the age of 2 years.
4. Do not use the Test after the expiry date or if the package has been damaged.
5. Store the Test components at a temperature between +4 °C and +30 °C. Do not freeze.
6. Use individual Tests once only.
7. In vitro diagnostic device for individual use.
8. 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.
9. 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.
10. After using, dispose of all components according to local laws. Liquid wastes should not be disposed of down the drain.
11. Do not open the sealed elements (test case, swab and tongue depressor) until just before performing the test. Take care to open as marked.
12. Do not switch the caps of the reagent vials.
13. All kit components are single-use, with the exception of the workstation (which can be re-used), the instructions for use and solutions 1 and 2, which must be stored, closed with their caps, at a temperature between +4 °C and +30 °C.
14. The operator is required to comply with the local regulations in force and to operate according to good laboratory practices (GLP).

MEDICAL DEVICES INSIDE THE KIT:

STERILE R
Sterile swab

Copan Flock Technologies Srl
Via F. Perrotti, 16/18
25125 Brescia - Italy
CE 0123

STERILE EO
Sterile tongue depressor

Kaltek Srl
Via del Progresso, 2
35127 Padova - Italy
CE 0476

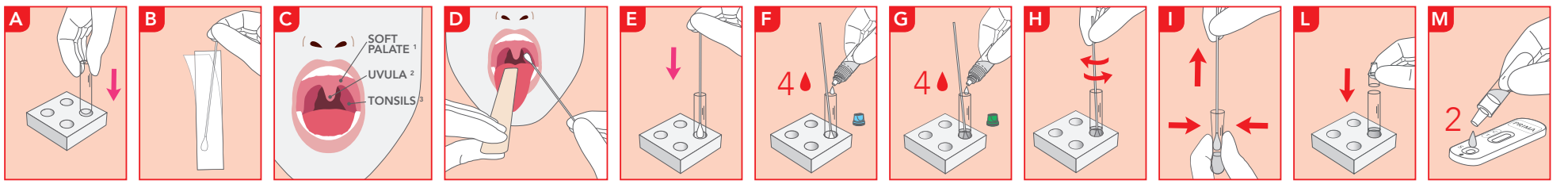
STERILE EO
Sterile tongue depressor

Jiangsu Suyun Medical Materials Co., Ltd
No.1 Medicine Line, Renmin Rd.
222002 Lianyungang - China
CE 0123

EC REP *Shanghai International Trading Corp. GmbH (Europe)*
Eiffestrasse, 80, D-20537 - Hamburg, Germany

SYMBOLS

IVD *In vitro diagnostic device*	*Legal manufacturer*		*Do not reuse*
Read the instructions before use	+4°C +30°C *Temperature limits*	REF	*List number*
STERILE R *Sterilised using irradiation*	Σn *Sufficient for <n> tests*	CE	*CE marking*
STERILE EO *Sterilized using ethylene oxide*	*Expiry date (last day of the month)*	LOT	*Lot number*
EC REP *Authorised Representative in the European Community*			



SPECIMEN EXTRACTION AND TEST PROCEDURE

WARNING: if purchasing a multipack, check that the sterile swab, the sterile tongue depressor, the test tube and the dropper have not been previously used (these disposable materials cannot be used twice).

1) Wash your hands with hot water and soap, rinse with clean water and dry.
2) Lay out the work tray on a clean, dry, flat surface. Place the empty plastic test tube in one of the compartments in the work tray. – FIG. A
3) 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 much 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
4) After collecting the sample, insert the swab's cotton tip into the supplied plastic test tube that you had previ¬ously placed in the workstation. – FIG. E
5) Open the vial STREP A RAPID 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
6) Next, open the vial STREP A RAPID 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.
7) 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
8) At the end of the incubation period, remove the test tube (with the swab and extraction fluid still in it) from the workstation. 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 one of the compartments in the workstation.
9) Add the supplied dropper to the plastic test tube. – FIG. L
10) 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.
11) **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 RESULTS AFTER 5 MINUTES. DO NOT READ THE RESULTS AFTER 10 MINUTES

POSITIVE

Two colored lines appear. A colored line should always appear in the Control (C) region and another line should be in the Test (T) region.
This result means that the test has detected the presence of *Streptococcus A* specific antigens in the sample. You should consult a physician.

NEGATIVE

One colored line appears in the Control region (C).
No apparent colored line appears in the Test line region (T).
This result is negative and means that no *Streptococcus A* antigens have been detected in the sample from the pharynx or that their amount is too low to be detected.

INVALID

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 the test with a new sample.

LIMITATIONS

1. The test procedure and the interpretation of the test result shall be carefully followed. Correct sample collection is essential for optimal test performance. Failure to follow the procedure may result in inaccurate results.
2. STREP A RAPID TEST is for in vitro diagnostic use only. The test should be used for the determination of *Streptococcus A* antigen on pharyngeal swabs only. It cannot determine either the quantitative value or the percentage increase in Streptococcus A antigen concentration.
3. This test only indicates the presence of *Streptococcus A* antigen in the specimen due to viable or non-viable *Group A Streptococcus* bacteria.
4. A negative result may be due to a *Streptococcus A* antigen concentration in the pharyngeal swab that is inadequate or below the detectable level of the test.
5. An excessive amount of blood or mucus on the swab may interfere with the test results and lead to a false positive result. Avoid contact of the swab with the tongue, cheeks and teeth and any oral areas with open wounds at the time of sampling.
6. As with all diagnostic tests, results should be interpreted in the light of the patient's overall clinical history.
7. If the reading time (5 minutes) is not strictly respected, wrong results may be obtained.

PERFORMANCE CHARACTERISTICS

Two swabs (test and reference method) were obtained from each patient and collected by physicians participating in the study. The comparator swab was analysed according to its instruction for use. The results were compared to those of the referece method and reported as positive and negative in Table 1. The performance of the test are reported in terms of Sensitivity, Specificity and Accuracy.

Table 1. Table of results.

	REFERENCE METHOD		
STREP A RAPID TEST	POSITIVE	NEGATIVE	
POSITIVE	29	2	31
NEGATIVE	3	163	166
	32	165	197

SPECIFICITY = (163/165) 100 = **98,79%** (CI 95%: 95,69 – 99,67%)
SENSITIVITY = (29/32) 100 = **90,63%** (CI 95%: 75,78 – 96,76%)
ACCURACY = (192/197) * 100 = **97,46%** (CI 95%: 94,20 – 98,91%)

CROSS-REACTIVITY

Each sample was tested as indicated below in Table 3, according to STREP A RAPID TEST instruction for use in force

BACTERIA	ATCC	LOT	CONCENTRATION ASSAYED
Bordetella pertussis	9340	BP-02	10^7 CFU/mL
Campylobacter jejuni	29428	CJ-02	10^7 CFU/mL
Candida albicans	MUT6298	CA-01	10^7 CFU/mL
Clostridium perfrigens	13124	CP-02	10^7 CFU/mL
Corynebacterium diphteriae	11913	CD-02	10^7 CFU/mL
Enterobacter cloacae	MUT6313	EC-02	10^7 CFU/mL
Helicobacter pylori	43504	HP-01	10^7 CFU/mL
Hemophilus influenzae	49766	HI-01	10^7 CFU/mL
Klebsiella pneumoniae	MUT6314	KP-02	10^7 CFU/mL
Proteus vulgaris	MUT6312	PV-02	10^7 CFU/mL
Pseudomonas aeruginosa	MUT6310	PA-02	10^7 CFU/mL
Shigella flexneri	12022	SF-02	10^7 CFU/mL
Staphylococcus aureus	MUT6311	SA-02	10^7 CFU/mL
Streptococcus agalactiae	12386	SAG-02	10^7 CFU/mL
Streptococcus disgalactiae	12388	SD-02	10^7 CFU/mL
Streptococcus gallolyticus	9808	SG-02	10^7 CFU/mL
Yersinia enterolitica	51871	YE-02	10^7 CFU/mL

None of the bacteria tested in this study, at the concentration given in the table, have shown cross reactions or interferences with STREP A RAPID TEST.

LIMIT OF DETECTION

The limit of detection study was conducted on Certified Positive ATCC Streptococcus pyogenes®.The LOD of STREP A RAPID TEST is 10^4 CFU/mL.