CLEARTEST® DIAGNOSTIK

MADE IN GERMANY

CLEARTEST® Strep A

Rapid test for the qualitative detection of streptococci antigen group A in throat swabs

For professional in-vitro-diagnostic use only.

CE IVD

INTENDED USE

The CLEARTEST® Strep A is a rapid visual immunoassay for the qualitative detection of streptococci antigen (group A) in throat swabs.

SUMMARY

Beta-hemolytic group A streptococci are the main reason for infections of the upper respiratory tract. Tonsilitis, Pharyngitis und Scarlet Fever are typical deseases. It has been shown that an early diagnosis and treatment of streptococci related Pharyngitis will reduce the severity of symptoms and decrease the amount of further complications like rheumatic fever or Glumerulonephritis. A conventional detection method by isolation of the streptococcus bacteria takes 4–48 hours, which is too long for a fast treatment. The CLEARTEST® Strep A facilitates a direct and efficient chairside diagnosis.

TEST PRINCIPLE

The CLEARTEST® Strep A is able to detect group A streptococci in throat swabs by color change of a color line (result line) which forms on the test strip. Polyclonal rabbit-anti-Strep A antibodies are immobilized on the test region of the membrane. The sample pad is coated with anti-Strep A antibodies conjugated to colored particles . During testing, the patient sample first reaches this reagion of the test strip. If Strep-A antigen is present in the sample, an antibody-antigen complex is being formed. This complex migrates along the membrane by capillary action and again reacts with the membrane-bound reagents. This is visible as a colored line in the test line region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. With proper test procedure, a colored line appears in the control region in any case. It shows that the correct amount of sample has been added, and the patient sample has been transported along the membrane.

PROVIDED MATERIAL

- CLEARTEST® Strep A test cassettes in pouch
- Pipettes
- Sterile polyester-coated applicators (swabs) STERILE EO CE 2797
  Puritan Medical Products Company LLC
  31 School Street, Guilford, Maine 04443-0149 USA
  EC REP EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands
- Extraction tubes
- Strep A Reagenz A: Sodium nitrite 1,0 M – **see „Precautions“!**
- Strep A Reagenz B: acetic acid 0,4 M
- Strep A positive control (1 mL) with in acticated streptococci A in a solution with BND as apreservative
- Strep A negative control (1 mL) with inactivated streptococci C in a solution with BND as apreservative
- Workstation

MANUAL

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND STABILITY

- The test may be stored at 2 °C–30 °C until expiry date.
- Do not freeze.
- Keep the test in the sealed pouch until using it.
- Prevent the test components from contamination.

PRECAUTIONS

- This test is meant for professional in-vitro diagnostic use only.
- Read the manual carefully prior to testing.
- Do not use the test if it has expired.
- Humidity and wrong temperature may influence the result negatively.
- Do not use the test if the pouch seems to be damaged.
- Only use each test cassette once.
- The test involves products of animal origin. Even certificates of origin and/or the health status of the animals can not completely guarantee the absence of communicable disease-causing ingredients. It therefore is advised to consider these products as potentially infectious and to takeprecautions
- Do not smoke, eat nor drink while handling specimens and test kits. All specimens should be considered potentially hazardous and be handled as infectious agents. Follow the best precautions against microbiological risks during the test execution. Wear protective clothing such as laboratory apron, disposable gloves and eye protection when specimens are examined.
- Avoid cross-contamination of samples by using a new sample vial for each sample collected. If there is an indication of microbial contamination or blood precipitates, the use of the test is not advised. Biological contamination of devices, sample containers or reagents can lead to false results.
- Do not touch the reaction window of the test cassette to avoid contamination.
- Do not mix or replace reagents from different lots.
- Dispose used test material in accordance with local regulations.
- Strep A Reagenz A:

Danger

H302: Harmful if swallowed.

P264: Wash hands thoroughly after handling.

P270: Do not eat, drink or smoke when using.

P301 + P312: IF SWALLOWED: Call a Poison Control Center or doctor if you feel unwell.

- Strep A Reagenz A & B or their mixture are slighlty acid. Avoid contact with eyes, cut and mucous membrane. In case of contact rinse thoroughly with water.

PREPARATION

- Bring test and all material to room temperature (15 °C–30 °C).
- Avoid contact of reagent bottles, applicators and extraction tubes with each other to prevent fromcross-contamination.
- Dab the back of the throat and tonsils with the sterile swab. Do not touch the tongue, cheek orteeth.
- Set the extraction tube into the workstation and fill 4 drops of Reagent A into it.

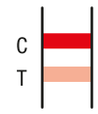
- Fill in 4 drops of reagent B. Mix the solution by rotating the tube gently.
- Insert the swab immediately with the sample collected in the tube.
- Turn and press the swab twice against the wall of the tube.
- Allow the tube with swab stand at room temperature for 1 minute. Then squeeze out as much liquid as possible from the swab by squeezing the swab tip again on the wall of the tube. Discard the swab. The mixture is now ready for testing. Best results will be obtained if you use the test within one our.

TEST PROCEDURE

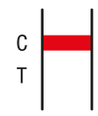
1. The test cassette and the solution should be at room temperature (15 °C – 30 °C). This is important as moisture may condense on the membrane, which would lead to a false result.
2. Open the package of the test.
3. Remove the test device from the seal.
4. Use the supplied dropper and apply 3 drops (about 70 – 100 µl) of the extracted solution from the vial to the sample well (S) of the test cassette.
5. Start the timer.
6. Read the result after 5-10 minutes. Do not read off any results after 15 minutes.

INTERPRETATION OF RESULTS

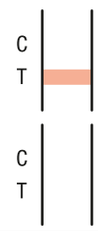
POSITIVE Two pink colored lines appear on the membrane. One line should be in the control region (C) and another line in the test region (T). The test has proven the presence of group A streptococci.



NEGATIVE Only one pink colored line appears in the control region (C). No visible line appears in the test region (T). There were no group A streptococci detected.



INVALID If the control line fails to appear in the control region (C), the test result is invalid. The absence of the control line may indicate an error in the test procedure or that the ingredients of the assay are not in order. Please repeat the test with a new test cassette, paying special attention to the instructions. If the problem persists, please contact themanufacturer.



QUALITY CONTROL

The test contains an internal quality control. The appearance of a control line in the control region (C) serves as an internal procedural control. It confirms sufficient specimen volume and correct technique.

It is recommended to perform positive and negative controls in accordance with good laboratory practice to confirm the test procedure and to verify proper test performance.

External controls can be carried out with the included positive and negative controls. Instructions: Add 4 drops of Reagent A and 4 drops of Reagent B to an extraction tube. Mix the solution by shaking. Then add two drops of the positive or negative control and mix the solution again with a swab. Leave the swab in the solution for at least 5 minutes. Then press the swab against the inner wall of the tube. Discard the swab. Continue with the instructions in the test execution point 2 on. Do not use the test if the control does not return the expected result. Repeat the test or ask your supplier.

LIMITATIONS

The test is suitable for the professional in-vitro-diagnostic use only and should be used for the qualitative detection of Strep A antigen only. Do not pay attention to the color intensity or width of each visible line.

As with all diagnostic tests, the results must be combined with all other clinical information available to the physician evaluated.

CLINICAL DATA

	Comparative test		
	Positive	Negative	Total
CLEARTEST® Strep A			
Positive	83	1	84
Negative	0	47	47
Total	83	48	131

Sensitivity: 99,9 % (95,6 – 100 %)*

Specificity: 97,9 % (89,1 – 99,6 %)*

Accuracy: 99,2 %

*95 % confidence interval

BIBLIOGRAPHY

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2. Levison, M and Frank, P. F.: Differentiation of Group A from other Beta Hemolytic Streptococci with Bacitracin, J. Bacteriol., 69, 284 – 287 (1995)
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4. Gupta, R., Talwar, G. P. and Gupta, S. K.: Rapid Antibody Capture Assay for Detection of Group A Streptococci Using Monoclonal Antibody an Colloidal Gold-Monospecific Polyvalent Antibody Conjugate, J. Immunoassay, 13, 441 – 445 (1992)
5. Ross, P. W.: Throat Swabs and Swabbing Technique, The Practitioner, 207, 791 – 796 (1971)

SYMBOLS

Index of symbols			
REF	Article number		Temperature limitation
	Observe operating instructions	LOT	Batch number
IVD	In-vitro-diagnostic		Expiry date
	Manufacturer		Content sufficient for <n> tests
	Dangerous substances		Single use
	Protect from heat and sunlight		Attention
	Protect from moisture		
	Do not use, if package is damaged		
CE	CE marked according to IVD directive 98/79/EG		

ORDERING INFORMATION

CLEARTEST® Strep A

Package with

5 test cassettes PZN 09746020 REF C3 10343-05

20 test cassettes PZN 02886433 REF C3 10343-20

IVD CE Created on: 2022-02-24 1-C3 10343-05ff-132-2-0005.1-2202

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