

Laboquick

Strep A Ag Test

Laboquick Strep A Antigen Test

One step, rapid test to determine Group A Streptococcal antigen from throat swabs. Only for Professional Use
Product Code: LSRA.01

Intended Use:

Laboquick Strep A Antigen cassette test is used as a diagnostic tool to detect qualitative immunochromatographic Streptococcus A Antigen in throat swab samples.

Summary:

Streptococcus are Gram Positive catalase negative round or oval shaped, smaller than $2 \mu\text{m}$, immobile, free of spores, when produced by hand in liquid feeding structures, forming an order like chain formed sequentially aligned, facultative anaerobic, glucose hexosidofosfat through by fermenting lactic acid-forming microorganisms. In particular, hyaluronic acid found in the streptococcus group consisting of capsules, micro-organisms found in enriched medium separated, and the new released. Streptococci; is quite common in nature; as can be found in the normal flora of the body as a saprophyte in foodstuffs such as milk and dairy products are also found. Also a variety of pathogenic human and animal infections can be caused by these organisms.

Test Principle:

Laboquick Strep A Ag Test is a membrane based and qualitative which can detect Streptococcus A Antigens in throat Swab samples. Step A Ag test shows a window which consists a sample pad that samples is dropped. Sample pad is kept with a porous membrane. Device has a membrane, consists coloured conjugate pad which has Strep A Polyclonal antibodies inside and (T) line coated with Strep A Antibodies and (C) line coated with Strep A goat antibody. If patient has Strep A Antigen is found in sample, Test (T) line will be produced. If there is no Strep A Antigen in sample, or it is below cut off point, Test (T) line will not be produced. On the other hand, there is a color line every time in the control space (C). This control line is a procedural indicator. It confirms that the sufficient sample solution is dropped, the sample expands in the test properly and reagent is under control.

Package content:

Strep A Ag Test Device, sample diluent bottle, chemical liquid agent to be added to diluent solution, sample taking swab rod, silica gel bag for moisture.

Storage Conditions:

Strep A Ag test should be kept under $2 \dots 30^\circ\text{C}$ degree. Never let it frozen. The product can be stored in stable condition until the date of expiry written on the product package unless it is open.

Warnings and Measures:

The following should be taken into consideration to get the correct results;

1. Before use, read the instructions carefully,
2. Only used in-vitro diagnostic
3. Never freeze the tests. If the test is stored in the refrigerator, you should provide the test to have the room temperature before use. The test should be completed under room temperature (between $15 \dots 30^\circ\text{C}$ degree)
4. Do not use the expired products.
5. Use the test device immediately after unpacked.
6. If the package of the test is damaged or torn, do not use the test device.
7. During the test, any cosmetics should not be used; any food or beverage should not be consumed and smoking should be avoided.
8. Prevent the possibility of any leaping of samples or producing the steam during the test.
9. It should be remembered that the best results can only be obtained depending on the proper conformance to the instructions.
10. Once the test procedure starts, every step should be taken without interruption.
11. To avoid splitting between samples, only use one diluent disposable bottle and swab rod for every individual patient.

Usage of Test Device

1. Unpack pouch by tearing the related part as shown.
2. Please check diluent liquid mixture preparation and sample collection parts.
3. Open the tap of diluent bottle, which comes with product and put swab rod inside of bottle. Stir the liquid in the bottle with rod for 30-60 seconds.
4. Close the tap of diluent bottle and shake it well.
5. By being sure that diluent bottle tap is looking upwards, break the part on tap carefully.
6. Drop 3-4 drops of sample dilution to sample well.
7. Read Test Results after 15-30 minutes. Do not take into consideration after 30 minutes.

Evaluation of the results:

8. The indication line taking part at the section marked with "C" in the result display confirms the NEGATIVE result.
- Two indication lines taking part at the sections both marked with "C" and "T" confirms the POSITIVE result.
- If any line is not appeared in the result display until the end of the testing time, the test is invalid. The test should be repeated.

Sample Used For This Test:

Fresh Human, Throat Swab Sample should be used for this test

Diluent Liquid Mixture Preparation:

Test Kit included 2 Liquid Diluent Bottles
Liquid Diluent Bottle is designed for individually every test and it will be used for main mixture bottle by adding Diluent B solution inside. Diluent B is provided only 1 for 25 tests.
After opening the cap of diluent bottle, 4 Drops of Diluent B shall be dropped inside Diluent bottle.
Diluent B cap shall be tightened firmly for keeping next patient. After this sample collection step shall be followed.

Sample Collection:

Sample which will be used for test, shall be taken by special, sterilized throat swab rod. After taking sample from different parts of throat the swab rod shall be put inside of diluent liquid bottle provided with product immediately. 30 - 60 Seconds stirring will be enough for antigen diluent mixture forming. After taking swab rod outside diluent liquid bottle, tap of bottle shall be tightened firmly.

Performance Characteristics:

		Laboquick Strep A Ag Test		Total
		+	-	
Culture Results	+	38	2	40
	-	3	65	68
Total		41	67	108

Sensitivity

Relative sensitivity of Laboquick Strep A Ag cassette test is determined as %95.

Specificity

Relative Specificity of Laboquick Strep A Ag cassette test is determined as %95.5

Test Limits:

1- Test Laboquick Strep A Ag test itself cannot be used to diagnose the disease. This test can only be used to detect the presence of Strep A antigens in the sample. The test results should definitely be supported by the supplement diagnosis and diagnostic methods with the expert comments.

2- In case the defects continue even if the test results are found negative, other various tests should be done by using the other clinical methods. Any result seen as negative does not remove the risk and possibility of Strep A infection.

3- Test device gives the best result under room temperature. Frozen samples can cause problems after brought to room temperature. In case of their including particles in solid form can block the membrane and the sample can cause a dark color at background. This can cause problems on reading the results.

4- The most productive completion of the test is depending on full conformance to the instructions. Otherwise the results may lead to faults.

5- More than 3-4 drops is applied on the sample hole of the test device can lead to faulty results.

References

1. Carapetis, Jonathan R.; Andrew C Steer, E Kim Mulholland, and Martin Weber (2005). "The global burden of group A streptococcal diseases". *The Lancet: Infectious Diseases* 5: 685-694.
2. "Group A Streptococcal (GAS) Disease". Centers for Disease Control and Prevention
3. "Streptococcal Infections (Invasive Group A Strep)". New York City Department of Health & Mental Hygiene. Retrieved 21 November 2012.
4. "Streptococcal Infections: What is Group A Streptococcus (GAS)?". Retrieved 21 November 2012.
5. "Streptococcal Infections (Invasive Group A Strep)". New York City Department of Health and Mental Hygiene. Retrieved November 21, 2012.

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