

Laboquick CANDIDA ALBICANS AG TEST

Laboquick Candida Albicans Ag Test

One step, rapid test to determine Candida Albicans antigens in vaginal swab samples. Only for Professional Use.

Product Code: LBCA.01

Intended Use:

Laboquick Candida Albicans Ag cassette test is used as a diagnostic tool to detect qualitative immunochromatographic Candida Albicans antigens in vaginal swab samples.

Summary:

Candida albicans is a diploid fungus and a causal agent of opportunistic oral and genital infections in humans. Systemic fungal infections (fungemias) have emerged as important causes of morbidity and mortality in immunocompromised patients.

Candida Albicans is commensal and is among the gut flora, the many organisms that live in the human mouth and gastrointestinal tract. Under normal circumstances, Candida albicans lives in 80% of the human population with no harmful effects, although overgrowth results in candidiasis. Candidiasis is often observed in immunocompromised individuals such as HIV-positive patients. Candidiasis also may occur in the blood and in the genital tract. Candidiasis, also known as "thrush", is a common condition, usually easily cured in people who are not immunocompromised. To infect host tissue, the usual unicellular yeast-like form of Candida Albicans reacts to environmental cues and switches into an invasive, multicellular filamentous forms.

Test Principle:

Laboquick Candida Albicans Ag Test is a membrane based and qualitative which can detect Candida Albicans Antigens in vaginal Swab samples.

Candida Albicans Ag test has 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 Candida Albicans Polyclonal antibodies inside and (T) line coated with Candida Albicans Antibodies and (C) line coated with Candida Albicans goat antibody. If patient candida Albicans antigen is found in sample, Test (T) line will be produced. If there is no Candida Albicans 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:

Candida Albicans Ag Test Device, sample diluent bottle, sample taking swab rod, silica gel bag for moisture.

Storage Conditions:

Candida Albicans Ag test should be kept under 2 ... 30°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 5.....30°C degree)
- 4-Do not use the expired products.
- 5-Use the test device immediately after unpackaged.
- 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 uninterruptedly.

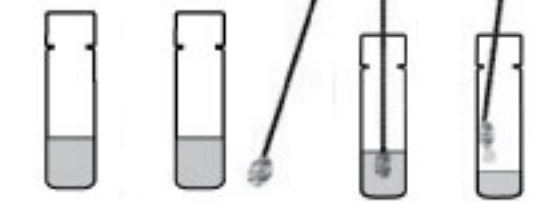
Test Usage Procedure:

1 Unpack pouch by tearing the related part as shown.



2 Check sample Taking Part.

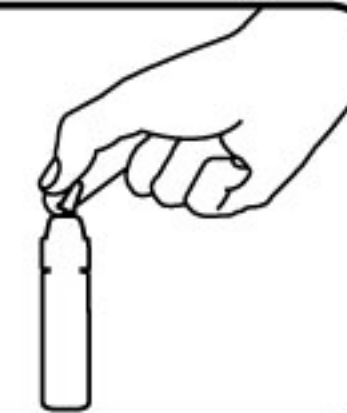
3 Open the tap of diluent bottle, which comes with product and put swab rod inside of bottle. Stir the liquid in the bottle with rod for 30-60 seconds.



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, Vaginal Swab Samples should be used for this test

Sample Collection:

Sample for test should be collected by special sterile vaginal swab rod. Swab rod which consists sample taken from different points of vagina is put into diluent bottle which is sent with product. It is shaken or stirred for 30 – 60 seconds. With this sample is dissolved in diluent liquid. After swab rod it taken out of diluent bottle and diluent bottle tap is closed.

Sensitivity:

Relative sensitivity of Laboquick Candida Albicans Ag cassette test is determined as %97.

Specificity:

Relative Specificity of Laboquick Candida Albicans Ag cassette test is determined as %100.

Test Limits:

- 1-Just Laboquick Candida Albicans Ag test itself can not be used to diagnose the disease. This test can only be used to detect the presence of candida albicans 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 candida albicans infection.
- 3- Test device gives the best result under room temperature
- 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.Candida albicans at NCBI Taxonomy browser, url accessed 2006-12-26
2. "Factors Affecting the Morphology of Candida Albicans" Dan Otho McClary Annals of the
3. Jones T, Federspiel NA, Chibana H, et al. (May 2004). "The diploid genome sequence of Candida albicans". Proceedings of the National Academy of Sciences of the United States of America 101 (19): 7329–34.
4. Butler, G., et al. (June 4 2009). "Evolution of pathogenicity and sexual reproduction in eight Candida genomes". Nature 459: 657-662. doi:10.1038/nature08064. PMID 19465905.
5. Rikkerrink E, Magee B, Magee P (1988). "Opque-white phenotype transition: a programmed morphological transition in Candida albicans". J. Bact. 170 (2): 895–899.

HAM.CAKK.01

Rev.01

Publishing Date: 18.08.2010

Manufacturer:

Köroğlu Tıbbi Malz. San. ve Tic. Ltd. Şti.
1776/23 Sok. No:4/A Mevlana Mah.
Bornova-İzmir-Turkey
Tel: +90 (232) 388 73 74
Fax: +90 (232) 388 40 43
www.koroglugroup.com
e-mail: medical@koroglugroup.com

