VITASSAY

Strep A

Rapid test for the qualitative detection of Group A *Streptococcal* from throat swabs.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Strep A is a rapid test, immunochromatographic, for the qualitative detection of Group A *Streptococcal* from throat swabs.

Simple, non-invasive and highly sensitivity assay to make a presumptive diagnosis of Group A *Streptococcal* respiratory infection.

INTRODUCTION

Group A *Streptococcus* is an important species of gram-positive extracellular bacterial pathogens. Group A *Streptococcus* colonize the throat or skin and are responsible for a number of suppurative infections and non-suppurative sequelae. They are the most common cause of bacterial pharyngitis and are the cause of scarlet fever and impetigo.

PRINCIPLE

Vitassay Strep A is a qualitative immunochromatographic assay for the detection of Group A *Streptococcal* from throat swabs.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Group A *Streptococcus*.

During the process, the sample reacts with the antibodies against Group A *Streptococcus*, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, the antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membrane and the blue control line always appears.

The presence of this blue line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Strep A**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

STORAGE AND STABILITY

The product should be stored and packaged at refrigerated or room temperature (2-30ºC/35.6-86ºF) on the sealed pouch. Thus optimal performance is guaranteed until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ 25 Tests/kit **Vitassay Strep A.** ▪ Reagent A (2M Sodium Nitrite). ▪ Reagent B (0.15M Acetic Acid). ▪ 25 Swabs. ▪ 25 Disposable pipettes. ▪ 25 Testing tubes. ▪ Instructions for use. ▪ Vitassay Strep A Positive Control swab + Instructions for use.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer.

SPECIMEN COLLECTION

Samples should be collected in clean and dry containers.

Samples should be process as soon as possible after collection. If this is not possible, the samples can be store in the refrigerator (2-8ºC/35.6-46.4ºF) for 8 hours prior testing.

Samples must be brought to room temperature before testing.

Homogenize the samples as thoroughly as possible prior to preparation.

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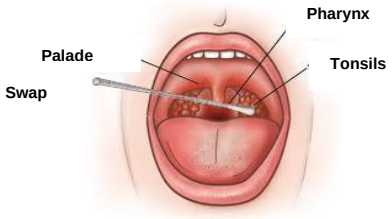
SPECIMEN PREPARATION

- Throat swab:

1. Remove the swab from its packing.
2. Collect specimen with a sterile swab from the tonsils and/or the back of the throat. Take care to avoid the teeth, gums, tongue or cheek surfaces.
3. Process the swab as soon as possible after collecting the specimen.

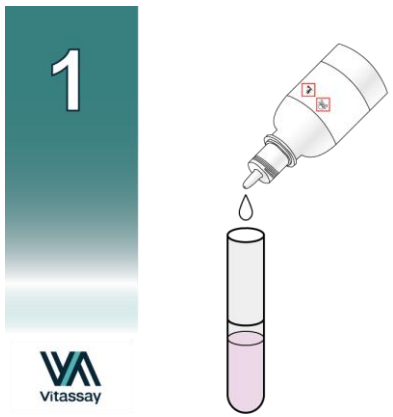


PROCEDURE

Allow the test, samples, controls and diluents to reach room temperature (15-30ºC/59-86ºF) prior to testing.

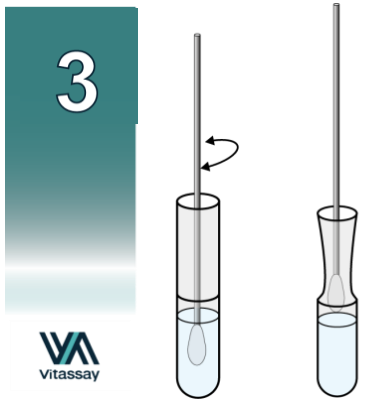
Do not open pouches until the performance of the assay

1. Add 5 drops Reagent A (light pink) (figura 1) and 5 drops Reagent B (figure 2) in a testing tube. The solution turn light yellow (colourless).
2. Immeditely insert the swab into the testing tube.
3. Mix the solution by rotating the swab forcefully against the side of the tube at least 1 minute. Best results are obtained when the specimen is vigorously extracted in the solution (figure 3). Extract as much liquid as possible from the swab, squeezing the sides of the tube or rotating the swab against the side of the tube as the swab is withdrawn. Discard the swab.
4. Remove the **Vitassay Strep A** from its sealed bag and using the pipette, dispense 4 drops from the testing tube into the circular window marked with letter S (figure 4).
4. Read the results at **10 minutes**. Do not read the test results later than 10 minutes.



Add 5 drops of Reagent A (light pink).

Add 5 drops of Reagent B (light yellow).



Put the swab into the tube, rotating 1 minute and extract the liquid.

Dispense 4 drops in the circular window marked with the letter S.

INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one blue line in the control zone (**C**)	There is no Group A *Streptococcal* presence. No infection caused by Group A *Streptococcal.*
	**POSITIVE** In addition to the blue line (**control line C**), a red line appears, (**test line T**)	There is Group A *Streptococcal* presence. Infection caused by Group A *Streptococcal.*
Any other result		Invalid result, we recommend repeating the assay using the same sample with another test. **Note:** Wrong procedural techniques, deterioration of the reagents or insufficient specimen volume are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

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QUALITY CONTROL

Internal procedural control is included in **Vitassay Strep A**. Blue line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

The colour of the liquid changes from light pink to light yellow (colourless) as you adds Reagent B to Reagent A. This is an internal extraction reagent control, and it indicates that you mixed the extraction reagent properly and that the reagents are functioning properly.

LIMITATIONS

- **Vitassay Strep A** must be carried out within 2 hours of opening the sealed bag.
- This test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group A *Streptococcus*.
- It should only be used with throat swabs. The use of other samples has not been established.
- The quality of **Vitassay Strep A** depends on the quality of the sample; Proper throat swab specimens must be obtained.
- The intensity of test line may vary from very strong at high depends on the antigens concentration.
- Positive results determine the presence of Group A *Streptococcus* infection. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated and must be based in the correlation of the results with further clinical observations.
- A negative result is not meaningful because of it is possible the antigens concentration in the throat samples is lower than the detection limit value. If the symptoms or situation still persist, it is recommended that all negative results undergo confirmatory testing using other method and/or virus identification by cell culture or PCR.

EXPECTED VALUES

It has been estimated that there are at least 517000 deaths each year due to severe Group A *Streptococcal* diseases (eg, acute rheumatic fever, rheumatic heart disease, post-streptococcal glomerulonephritis, and invasive infections). The prevalence of severe Group A *Streptococcal* disease is at least 18.1 million cases, with 1.78 million new cases each year. The greatest burden is due to rheumatic heart disease, with a prevalence of at least 15.6 million cases, with 282000 new cases and 233000 deaths each year. On a global scale, Group A *Streptococcal* is an important cause of morbidity and mortality.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation, with throat specimens, was performed comparing the results obtained by **Vitassay Strep A** and another rapid test commercial available (OSOM® Strep A Test, Genzyme Diagnostics).

The results were as follows:

		OSOM® Strep A Test		
		Positive	Negative	Total
Vitassay Strep A	Positive	4	0	4
	Negative	0	20	20
	Total	4	20	24

Vitassay Strep A vs OSOM® Strep A Test			
Sensitivity	Especificity	VPP	VPN
>99%	>99%	>99%	>99%

The results showed a high sensitivity and specificity to detect Group A *Streptococcal* using **Vitassay Strep A**.

Cross reactivity

No cross reactivity against organisms that cause other respiratory infections is detected:

Influenza type A	*Adenovirus*
Influenza type B	*Group D Streptococcus*: Enterococcus

REFERENCES

1. MADELEINE W. CUNNNGHAM. "Pathogenesis of Group A *Streptococcal* Infections".Clinical Microbiology Reviews, July 2000, p. 470-511.

2. JONATHAN R. CARAPETIS; ANDREW C. STEER; E KIM MULHOLLAND; MARTIN WEBER. "The global burden of Group A *Streptococcal* diseases". The Lancet Infectious Diseases, Nov 2005, Vol. 5, Issue 11, p. 685-694.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number

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