

Salistick™

Saliva Pregnancy Test - Instructions for use

The **Salistick™** saliva pregnancy test is a rapid pregnancy self-test, which can be easily performed at home. It detects the presence of the pregnancy hormone, hCG (human chorionic gonadotropin) in saliva 1 day after a missed period, when the menstrual period is regular.

Salistick™ Saliva Pregnancy Test can be used any time of the day (30 minutes after drinking or eating).

6 Steps to follow:

1. After reading this insert and when you are ready to perform the test, remove the Collection Handle and Analytical Unit from the sealed pouch. Perform this test immediately after opening. The Collection Handle includes a sample sufficiency indicator, which will change to a blue colour when sufficient saliva has been collected.

» Perform this test immediately after opening.

2. Saliva collection

Allow saliva to pool in your mouth for at least 30 seconds. To collect the saliva sample place the Collection Foam in your mouth for **90 seconds**. Whilst collecting the saliva, roll the Collection Foam from side to side a few times to increase saliva absorption.

» Do not chew or bite the collection foam !

90
seconds



3. Indicator colour change

» After 90 seconds take the Collection Foam out of your mouth, hold it vertically and confirm that the indicator has changed to a blue colour.

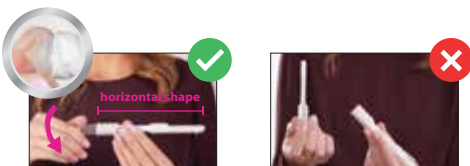
» Note: the colour change is not indicative of the test results.

If a blue colour is not visible, repeat the process until the indicator changes to blue.



4. Insert the Collection Foam into the Analytical Unit, and turn the Collection Handle clockwise **while holding horizontally**, until both units are secured.

» Do not reopen.



5. Lay the **Salistick™** saliva pregnancy test on a flat clean surface with the Result Window facing up.

A transparent or pink liquid may be seen migrating along the Result Window. This indicates that a sufficient amount of saliva was collected.

» Read your result within 5-15 minutes from connecting the Collection Handle to the Analytical Unit. The results should not be read after 15 minutes.

» A result may appear as early as 5 minutes.



6. The results

PREGNANT:

TWO PINK LINES in the Result Window (both C and T region).

One line may be lighter than the other.

Appearance of the results may vary.



NOT PREGNANT:

ONE PINK LINE in the Result Window (only C region).



INVALID RESULT:

No control line (C region).

The test did not work. This may be the result of an incorrect test procedure. You are advised to repeat the test.



Warnings and Precautions

PLEASE READ ALL THE INFORMATION PRESENTED IN THIS INSERT BEFORE PERFORMING THE TEST.

- For saliva use only
- Single-use device. Do not reuse
- For in-vitro diagnostics use
- Intended for self-testing
- For external use only
- Do not use after the expiration date stamped on the side of the package box
- Keep out of the reach of children
- Store in a dry place at room temperature (15 °C - 25 °C).
- Do not freeze
- Do not use if the foil pouch or outer package is damaged
- **Wait at least 30 minutes after eating or drinking of any kind**
- At 1 day after missed period approximately 5% of women may have a false negative result. The accuracy of the device will improve with testing after the 1st day after missed period. If you think that you are pregnant you should repeat the test in 24-48 hours to improve the detection of low levels of hCG in your saliva.

About the Test

Saliva is a complex fluid which contains many biological markers and a variety of hormones. The levels of these hormones are significantly lower than in serum/blood or urine. Therefore, only an extremely sensitive test will enable their detection ⁽¹⁻⁴⁾.

When you are pregnant, your body produces the pregnancy hormone, hCG (human chorionic gonadotropin). A portion of this hormone travels from the blood to the saliva. Salignostics has developed the unique **Salistick™** saliva pregnancy test .

Salistick™ saliva pregnancy test can detect low levels of hCG in saliva. The kit is based on a lateral flow immunoassay (LFIA).

This is the same principle used by other pregnancy tests.

In laboratory testing with saliva samples of pregnant women 1 day after their missed period, Salistick™ saliva pregnancy test gave over 95% positive results.

When to use the Test

Salistick™ saliva pregnancy test can detect hCG (human chorionic gonadotropin) in saliva 1 day after your missed period, when your period is regular. You can use the test at any time of the day (30 minutes after drinking or eating).

Kit contents

Instructions for use and a sealed pouch with a Collection Handle, Analytical Unit and a preservative silica bag, materials required but not provided: Timer.



Intended Use

The Salignostics **Salistick™** saliva pregnancy test is an in vitro diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) in saliva. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for Over-The-Counter (OTC) use.

How does the test work?

The Collection Foam absorbs saliva from your mouth. When you connect the Collection Handle to the Analytical Unit, the saliva is squeezed and migrates along a special membrane until it reaches the test zone. In the presence of hCG hormone, two coloured lines will appear in the results window (C and T). In the absence of the hormone within the saliva sample only one coloured line, the control line (C) will appear.

This control line will appear if the test was performed correctly.

Questions and answers

Q: How does the test work?

A: When you are pregnant, your body produces the pregnancy hormone hCG. The amount of hCG in your body increases in the early stages of pregnancy. The **Salistick™** saliva pregnancy test detects this hormone in saliva.

Q: When can I test with the Salistick™ saliva pregnancy test?

A: The **Salistick™** saliva pregnancy test is designed to detect the hCG pregnancy hormone levels 1 day after your missed period. This hormone increases as pregnancy progresses.

Q: How accurate is the test?

A: In laboratory testing with saliva samples of pregnant women 1 day after their missed period, **Salistick™** saliva pregnancy test gave over 95% positive results.

Q: What do I do if the result is positive (pregnant)?

A: A positive (pregnant) test result shows that the pregnancy hormone (hCG) was detected in saliva. You should see your doctor to confirm that you are pregnant (the test does not substitute a doctor's diagnosis). If you test positive, but think you may not be pregnant, you should check with your doctor.

Q: What do I do if the result is negative (not pregnant)?

A: You may not be pregnant, or the hCG levels might be below the limit of detection of the test and therefore too early to test. If you do not start

your period within two days, you should retest with another test. It is possible that you miscalculated the length of your cycle, or your saliva may not have contained enough hCG. If upon retesting you get another negative result and your period has still not started, you should consult your doctor.

Q: I have waited longer than 10 minutes and still there is no line in the Result Window. Is there anything wrong?

A: Your result should appear within 5-15 minutes. The control line (C) should appear in the Result Window, to indicate that the test was performed correctly. If not, the test is not valid. This could be due to insufficient saliva that was collected, or not placing the device horizontally after connecting the Collection Handle to the Analytical Unit. You should retest with a new kit carefully following all instructions.

Q: Will the result change if left standing for additional time?

A: The test result should be read within 5-15 minutes. Do not read the results after 15 minutes.

Q: Do any drugs or medications affect the test?

A: Only medications containing the pregnancy hormone, human chorionic gonadotropin (hCG), can affect the result. The test should not be affected by other hormone therapies, alcohol, pain killers, antibiotics, or the contraceptive pill.

Performance characteristics

1. Analytical Sensitivity

SalisStick™ saliva pregnancy test will display positive results with saliva sample containing hCG at levels of 0.75 mIU/mL or greater.

2. Clinical Sensitivity and Specificity

A study was performed to evaluate the clinical performance of the **SalisStick™** saliva pregnancy test, when compared to the true pregnancy status. In samples collected 1 day after a missed period (two days after the due date for the period), the **SalisStick™** saliva pregnancy test demonstrated a sensitivity of %95.16 (CI: %86.5% - 98.9) and specificity of %97.30 (CI: %90.6% - 99.7).

2% of women may have a false positive when using the device' i.e. getting a positive result from the test when you're not pregnant.

3. Specificity

The following compounds exhibited no interference when dissolved in saliva samples, which had hCG levels of 0 mIU/mL and 1.5 mIU/mL:

hFSH 200 mIU/mL

hLH 5 mIU/mL

hTSH 10 µIU/mL

Substance	concentration	Substance	concentration
Acetaminophen	60 µg/mL	Caffeine	0.3 mg/mL
Acetylsalicylic acid	60 µg/mL	Ethanol	6% v/v
Atropine	30 µg/mL	Nicotine	0.036 mg/ml
Gentisic acid	30 µg/mL	Cranberry juice	6% v/v
Ampicillin	30 µg/mL	Sugar	2% (20 mg/ml)
Tetracycline	10µg/mL	Table salt	0.50% (0.5 mg/ml)
Ibuprofen	48µg/mL	Sodium glutamate	0.10% (1mg/ml)
Estriol	10µg/mL	Milk	6% v/v
Cough Syrup	6% v/v	Mouthwash	6% v/v
Biotin	1200 ng/mL	Orange Juice	6% v/v
Amylase	Add 250 µg/ml	Soft drink (coke)	6% v/v
IgA	10µg/mL	Tea (dark)	6% v/v
Whole Blood	6% v/v	Black Coffee	6% v/v
Glucose	2%	Water	6% v/v
Bilirubin	0.05 mg/ml	Sodium Bicarbonate	6% v/v (60mg/ml)
Cholesterol	0.45 mg/ml	Hydrogen Peroxide	6% v/v
F- globulin	0.8mg/ml	hCG βcf	10 pmol/ml

Bibliography

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- Scolaro, K. L., Lloyd, K. B., & Helms, K. L. (2008). American Journal of Health-System Pharmacy, 65(4), 299-314.
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Dispose the test kit

Dispose of the used device in the bin 

Additional information

To increase your chances of a healthy pregnancy

- Maintain a well-balanced diet.
- Avoid smoking or drinking alcohol.
- See your healthcare professional for proper care and nutrition counselling.

	Manufacturer		Do no use if package is damaged
	Consult instructions for use		Do not re-use
	Catalogue or model number		Disposal
	Use by/Expiry date		Keep dry
	For in Vitro diagnostic use only		Lot number
	Storage temperature		Number of tests in pouch

SLS000001
RA004_UA_SSG Rev.02

SalisStick™
Anywhere, Anytime

Scan me
to access
instructional
video



For more information contact

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1ST Time
With
Saliva

SupaMedPRO

Exclusive Australian Sponsor and
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SalisSwab Saliva Collection Unit
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