Saliva Pregnancy Test Kit

BioTeke
USER INSTRUCTION

·1. Read this instruction guide carefully.
·2. Prepare a watch(or a clock/timer), tissues and either hand sanitizer or soap and warm water.
·3. Check the test kit contents. Make sure that nothing is damaged or broken.

-Please read the instructions carefully before you begin testing.

Test Card　　User instruction

PRE-TEST PREPARATION

- Note: Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
- Note: Materials required but not provided
  （1） Watch (or a clock/timer),
  （2） Tissues,
  （3） Hand sanitizer / soap.

1

Wash your hands thoroughly for at least 20 seconds before the test.

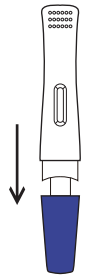
2

Keep your mouth clean for **at least 30 minutes** before the test, and limit your diet (including drinks, coffee, food, etc.), smoking, alcohol,or oral spray.

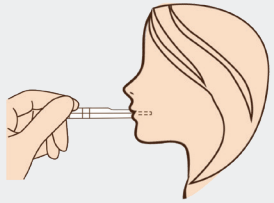
TEST PROCEDURE

3

Remove the test device from the sealed foil pouch and remove the cap by pulling.
This will expose the absorbent collection pad. Use device within one (1) hour of opening.
Best results will be obtained if the test is performed immediately after removing the test device from the foil pouch.



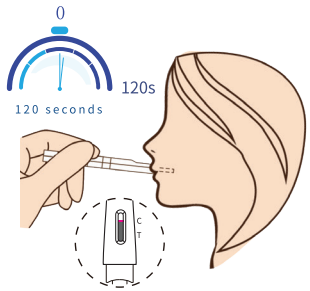
4



Hold the end of the device and place the absorbent collection pad into the mouth. Gently rub the collection pad on the cheek and tongue in circular motions(approximately 10-15 times).

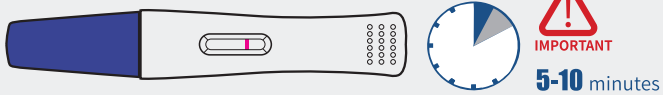
5

Place the collection pad under the tongue (with lips closed) for approximately two (2) minutes.
During this time, observe whether a line is visible in the C (control) region of the device test window. If not, repeat the above process until a line in the C region is visible. Once a line is visible in the C region, remove the device from the mouth and replace the cap.



6

Then place the device on a flat/ level surface. Read the test result in 5-10 minutes. Do not interpret the result after 15 minutes.
Note: Keep the test device level during sampling. The hand-held part should not be lower than the sponge. Do not move the test device around during testing or whilst awaiting your result.



7 Results Interpretation

IMPORTANT

NOTE:
The test results should not be read after 15 minutes.

(Positive)

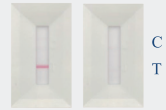
Positive (pregnant): two red reaction lines, i.e. one red reaction line in the test area (T) and one red reaction line in the control area (C). If the color of the test area (T) is very weak, it means that you may be pregnant, please retest on the next day.

(Negative)

Negative (not pregnant): one red reaction line, i.e. only one red reaction line appears in the control zone (C).

(Invalid)

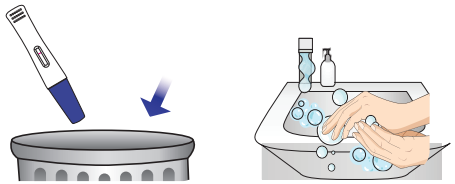
Invalid: No red line appears in the control area (C), indicating that the test is wrong or invalid. Please read the instructions carefully and retest, if the problem still exists, please contact the manufacturer.



Note: The chromaticity of the control line and the detection line can be different depending on the amount of HCG in the saliva, when the HCG concentration is very high, the detection line (T) is very obvious, and the control line (C) may become very weak, due to the HCG concentration is too high, there is a "hook" effect that will make the color of the detection line (T) lighter, which is a normal phenomenon, and the control line (T) may become very weak. If you want to get a stronger positive result, you can dilute the test and re-test.

8

Discard all used test components in the trash.



USER INSTRUCTION

Saliva Pregnancy Test Kit

PRODUCT NAME

Saliva Pregnancy Test Kit

PACKAGE SPECIFICATION

1 Test/Kit; 5 Tests/Kit

INTENDED USE

The Saliva Pregnancy Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in saliva to aid in the early detection of pregnancy.

TEST PRINCIPLE

Human chorionic gonadotropin (HCG) is a glycoprotein produced by the placenta during pregnancy, which can enter the whole body through the blood circulation of pregnant women. Saliva is known to be very similar to its blood components, so it can be used as a test of human chorionic gonadotropin (HCG). The content of HCG changes with the growth of the embryo. In normal pregnancy, HCG can be detected in saliva after 7 to 10 days after conception, which can assist in the diagnosis of early pregnancy.

The test strip uses a double antibody sandwich immunochromatographic method and consists of a nitrocellulose membrane coated with anti-α-HCG monoclonal antibody and anti-mouse IgG polyclonal antibody, and a latex microsphere binding pad labeled with anti-β-HCG monoclonal antibody, as well as other reagents. The LoD of this product is 5 mIU/mL.

For detection，saliva samples are chromatographed upward under capillary effect. If positive, the HCG in the specimen first binds to the latex microsphere-labeled HCG antibody during the chromatography process to form the HCG-antibody-latex microsphere complex. Then, the complex will continue to chromatograph and bind to the α-HCG antibody fixed on the membrane, resulting in a red band appearing in the detection line area (T). If negative, there will be no red band in the test line area (T). With or without HCG in the sample, a red band should appear in the quality control area (C) to prove the validity of the test results.

MATERIALS PROVIDED

Components	Loading quantity (Specification)	
	1 Test/Kit	5 Tests/Kit
Test Card	1pc	5pcs
User instruction	1pc	1pc

STORAGE CONDITIONS AND SHELF LIFE

This kit should be stored at 2°C~30°C,valid for 24 months. Do not refrigerate.Test cards should be used within 1 hour after opening the foil pouch.

Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

Keep your mouth clean for 30 minutes before the test, and limit your diet (including drinks, coffee, food, etc.), smoking, alcohol,or oral spray.

LIMITATIONS OF THE TEST

1. This test kit is used to qualitatively detect the presence of HCG in women's saliva specimens, and the concentration of HCG in the test specimens cannot be judged by the chromaticity of the test lines and control lines.
2. Uterine tumors, hydatidiform mole or menopause people may have positive results due to their high HCG levels.
3. Low concentrations of HCG (<50 mIU/mL) will occur quickly after conception. However, after termination of pregnancy, HCG testing is positive for several weeks due to natural (spontaneous delivery) or unnatural (spontaneous abdominal birth, habitual abortion, or medical abortion).
4. Other conditions including trophoblastic disease or non-trophoblastic neoplasia (such as testicular, prostate, breast, and lung cancer) can also cause increases in HCG concentrations. If the multiple test results and the expected results are inconsistent, a physician must be consulted.
5. Extrauterine pregnancy produces very low levels of HCG, and negative results cannot rule out ectopic pregnancy. If doubt remains, testing is recommended.
6. Drugs containing HCG that interfere with the detection of this test paper will produce the wrong early pregnancy results.
7. Stale or contaminated samples can interfere with test results.

PERFORMANCE CHARACTERISTICS

1. The width of the membrane strip of this kit is not less than 2.5 mm, and the migration speed is not less than 10 mm/min.
2. Negative/positive reference coincidence rate

All the positive references are positive, which is consistent with the known results of the reference; all the negative references are negativ.

3. Repeatability

Repeated testing was conducted for national or enterprise repeatable reference products for 10 times. The test results were consistent with the known results of the reference products and were uniform in color.

4. Limit of Detection(LoD)

The Limit of Detection(LoD) of Saliva Pregnancy Test KIT is 5mIU/mL.

5. Crossreactivity&MicrobialInterferencestudy

No cross-reactivity with 500 mIU/mL human luteinizing hormone (hLH), 1000 mIU/mL human follicular estrogen (hFSH), and 1000 μIU/mL human thyrotropin (hTSH)

6. Hook effect

No high dose hook effect was observed when testing up to aconcentration of 15000mIU/mL.

PRECAUTIONS

1. This is a single-use in vitro diagnostic reagent, do not reuse, and do not use expired products.
2. Do not use the aluminium foil bag if it is damaged.
3. Do not open the sealed foil pouchbefore use and use it as soon as possible after opening the aluminium foil bag.
4. The aluminum foil bag contains desiccant and must not be taken orally.
5. Operate at room temperature.Test cards kept at low temperature should be restored to room temperature beforeopening to avoid moisture absorption.
6. An unclean oral environment, such as diet (including drinks, coffee, food, etc.), smoking, or oral sprays can lead to false results. Repeat the test if necessary.
7. The presence of HCG cross-reactive substances in the saliva of menopausal patients can cause false positive results.
8. If the saliva test is negative and the pregnancy is still suspected, can be retested after 48 to 72 hours.
10. The hook effect may occur when the HCG concentration exceeds 15000mIU / mL, and the test results may be negative, and should be diluted before testing.
11. Patients with uterine tumors and hydatidiform mole may have positive results due to their high HCG content, please confirm the diagnosis in combination with clinical experiments.
12. Please dispose of the used test cards properly and do not discard them at will.
13. The final diagnosis should be made by the doctor after integrating the test indicators and clinical symptoms.

REFERENCES

1. Wang Yongjin, Modern Clinical Laboratory Science [M], Beijing: People's Military Medical Press, 2001 :190.
2. Lin Min, Human chorionic gonadotropin detection and clinical application [U], Laboratory Medicine and Clinics, February 2009, Volume 6, Issue 4, 281~283.
3. Ye Yingchong, Shen Ziyu, et al, National Clinical Laboratory Procedures [M], Third Edition, Nanjing: Southeast University Press, 2006:520.
4. Chen Huagen, Huang Xuebin et al, Problems and Countermeasures in Quantitative Determination and Clinical Application of Human Chorionic Gonadotropin [J], Medical Theory and Practice, 2011, Volume 24, Issue 24, 2937~2938.

SYMBOLS

Date of manufacture	Keep away from sunlight
Manufacturer	Keep dry
Do not re-use	Temperature limit (2°C / 30°C)
IVD *in vitro* diagnostic device	Contains sufficient for <n> test
Use-by date	Consult instructions for use
LOT Batch code	Do not use if package is damaged
CE mark	

BioTeke Corporation（Wuxi）Co.，Ltd.
No. 90, Huiming Road, Huishan, Wuxi City, Jiangsu, 214000, China

EC REP MedUnion S.L.
Carrer de Tapioles,33,2-1,08004，Barcelona，Spain

● Revision date: May 9,2025
Edition: B2

图纸名称	人绒毛膜促性腺激素(HCG)检测试剂盒(乳胶法)说明书(口含式英文)	文件号	RD2235-04-029-B2	材质	双胶纸
尺寸	A4	色号	见图纸		
设计/日期		审核/日期		批准/日期	