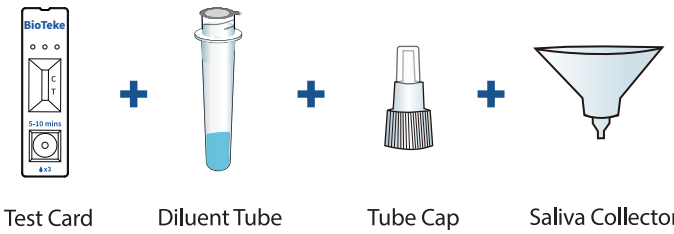
Saliva Pregnancy Test Kit

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.
-For self-testing



PRE-TEST PREPARATION

- Note: Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
- Note: Testing should be conducted under conditions of 10–30°C and 20–75% relative humidity.
- 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

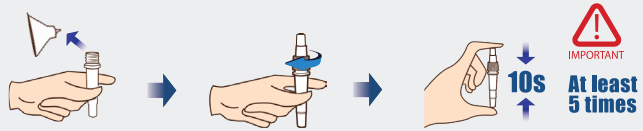
Remove the Diluent Tube,gently peel off the aluminum foil seal and insert the Saliva Collector into it.

4

Spit saliva from the mouth (tongue against the palate, which tends to secrete saliva) into a Saliva Collector and observe the liquid level in the Diluent Tube,the volume of saliva should be as consistent as possible with the sample diluent.

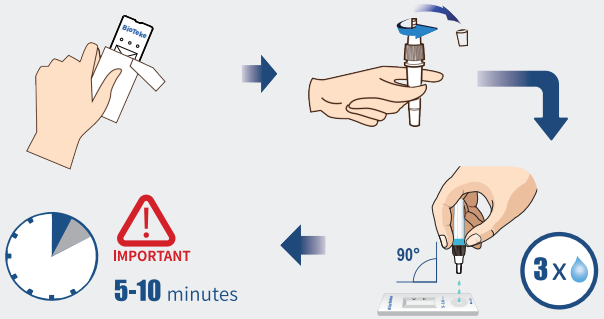
5

Gently remove the Saliva Collector, screw the Tube Cap, Upside down mixing for at least 10 seconds(at least 5 times), and let the sample mix as well as possible.



6

Open the pouch and take out the Test Card. Place it on a flat, dry and clean surface. Unscrew the top white cap.Turn the tube integrated dropper cap upside down and slowly squeeze 3 drops onto the sample well of the Test Card.



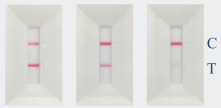
7 Results Interpretation

IMPORTANT

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

(Positive)

Positive (pregnant): two red reaction lines, 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.

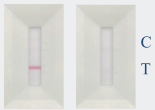


(Negative)

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

(Invalid)

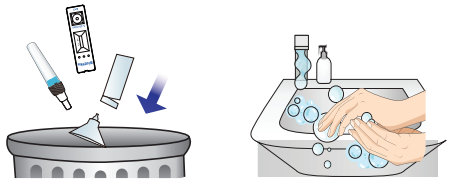
Invalid: No red line appears in the control area (C), indicating that the test is wrong or invalid. Please read the instructions carefully and retest, if the problem still exists, please contact the manufacturer.



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.



BioTeke CE 3018

USER INSTRUCTION

For self-testing

Saliva Pregnancy Test Kit

PRODUCT NAME

Saliva Pregnancy Test Kit

PACKAGE SPECIFICATION

1 Test/kit; 2 Tests/kit; 5 Tests/kit; 20Tests/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 immuno-chromatographic 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 0.5 mIU/mL.

For detection, an appropriate amount of treated saliva samples is dropped into the sample well and chromatographed upward under capillary effect. If positive the HCG in the specimen first binds to the latex microsphere labeled anti-β-HCG monoclonal antibody during the chromatography process to form the HCG-anti-β-HCG monoclonal antibody-latex microsphere complex. Then, the complex will continue to chromatograph and bind to the anti-α-HCG monoclonal 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	Main Ingredients	Loading quantity (Specification)			
		1 Test/Kit	2 Tests/Kit	5 Tests/Kit	20Tests/Kit
Test card	Test strip containing specific Murine anti-α-HCG monoclonal antibody, Murine anti-β-HCG monoclonal antibody and Anti-mouse IgG polyclonal antibody.	1 pc	2 pcs	5 pcs	20 pcs
Diluent Tube (0.5mL)/pc	0.9% NaCl solution	1 pc	2 pcs	5 pcs	20 pcs
Tube cap		1 pc	2 pcs	5 pcs	20 pcs
Saliva Collector		1 pc	2 pcs	5 pcs	20 pcs

AUTOMATED OR NOT

Not automated

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 0.5 mIU/mL.

5. Cross reactivity

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

6. Interfering substance: The following interfering substances will also not interfere with the results of the kit:

No.	Interference substance sample	No.	Interference substance sample
1	1% Mucin	10	5% Ethanol
2	5% Human blood	11	0.05 mg/mL Bilirubin
3	10% Mouthwash	12	0.5 mg/mL Cholesterol
4	10% Mint	13	20 mg/mL Triglyceride
5	10% Food waste (Glucose、Organic Acids)	14	30μg/mL Amoxicillin
6	10% Toothpaste	15	5 ng/mL Budesonide
7	120 IU/mL Rheumatoid Factor	16	40ug/mL Dydrogesterone
8	1:100 Heterophilic Antibodies	17	0.4ug/mL Folic Acid
9	40mg/L Lysozyme	18	0.2 mg/mL Ibuprofen

7. Hook effect

When the HCG concentration exceeds 188,600 mIU/mL, weak positive or false negative results may occur.

8. Clinical study

Saliva Pregnancy Test Kit	Comparative reagent kit		
	Positive	Negative	Total
Positive	148	0	148
Negative	2	153	155
Total	150	153	303

Statistics	Value	95%CI
Diagnostic sensitivity	98.67%	(95.27%-99.84%)
Diagnostic specificity	100.00%	(97.62%-100.00%)
Accuracy	99.34%	(97.64%-99.92%)

9. hCG Isoform Relative Recognition

Based on a double-antibody sandwich principle, this test detects intact hCG molecules retaining the α-β dimeric structure and shows limited recognition of free subunits and fragments. See table below:

LOD: 0.5 mIU/mL = 1.09 pmol/L intact hCG (traceable to WHO 5th IS 07/364).

Isoform	WHO International Standard	Equimolar conc.(pmol/L)
Free β-subunit	99/650	440
Free α-subunit	99/720	84000
β-core fragment	99/708	>1020000

10. This assay is calibrated with standards traceable to the 5th WHO IS for hCG (07/364). Cross-reactivity verification used standards traceable to WHO IS for TSH (81/565), FSH (92/510), and LH (81/535). Relative recognition was determined using WHO Reference Reagents free β-hCG (99/650), free α-hCG (99/720), and β-core fragment (99/708).

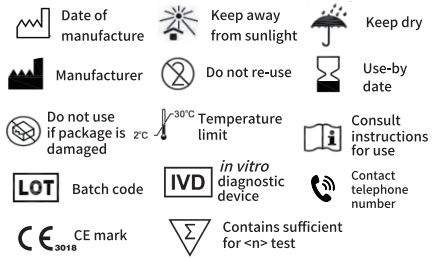
PRECAUTIONS

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 pouch before 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 before opening to avoid moisture absorption.
6. Use fresh specimens for testing, do not use repeated freeze-thaw samples.
7. 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.
8. The presence of HCG cross-reactive substances in the saliva of menopausal patients can cause false positive results.
9. If the saliva test is negative and the pregnancy is still suspected, the saliva can be collected again and measured again after 48 to 72 hours.
10.If the sample HCG concentration exceeds 188,600 mIU/mL, a hook effect may occur, causing weak positive or false negative results. When a weak positive result is doubtful, repeat the test the following day; a weaker line suggests a hook effect, while a stronger line makes it less likely. If suspicion remains, dilute the sample with saline by 2-fold (equal volume mixing) or 4-fold (serial twofold dilution) and retest. A stronger T line after dilution indicates a possible hook effect, whereas a weaker or disappearing line supports the original result. This may occur around the 9th week (about two months after the last menstrual period) or later in some pregnancies, though timing varies. These steps are for preliminary investigation only and not a substitute for professional diagnosis. If pregnancy is still suspected after negative results, consult a healthcare professional.
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.
14.Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user is established.
15.The quality of the sampling technique and the specimen processing have a great impact on the detection of human chorionic gonadotropin (HCG) included in this test kit.
16.The test results of this kit can only serves reference for clinicians and should not be used as the sole basis for a clinical diagnosis.
17.Do not mix use different batches of test cards and diluent tube.
18. If you require the Safety Data Sheet (SDS), please contact us by phone or email.
19.If you have oral bleeding or are taking hormonal drugs, do not use this product for testing.

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



CHANGE HISTORY

Edition	Revision date	Reason for change
A0	Jul 13, 2026	Initial Release

EU REP MedUnion S.L.
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