

HCG Pregnancy Test (Colloidal Gold)

[Intended Use]

The HCG Pregnancy Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

The HCG Pregnancy Test (Colloidal Gold) is designed for both self-testing and professional laboratory use, not for near patient testing.

[Model]

Cassette, HCG-UST-01

[Test Principle]

The HCG Pregnancy Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The assay is conducted by filling the urine specimen to sample well and observing the formation of red-colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-HCG-colored conjugate and form a red colored line at the test line region of the membrane. The absence of this red colored line suggests a negative result. To serve as a procedural control, a red colored line will always appear in the control line region if the test has been performed properly.

[Warnings and Precautions]

1. For *in vitro* diagnostic use.
2. This product is only intended for female use in pregnancy testing.
3. Do not use test kit beyond the expiry date.
4. The test device should not be reused.
5. The test kit should remain in the sealed pouch until use. Do not use if the pouch is damaged or opened.
6. The used test kit can be disposed of with normal household waste in compliance with the applicable local regulations.
7. 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 and/or you are established.
8. This reagent is designed for the qualitative screening test. A confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

[Materials and Components]

Materials provided

- 1) Test device
- 2) Dropper
- 3) Instruction
- 4) Collection container (Optional)

Materials required but not provided

Timer.

[Reagents]

Coated Antibodies: Control region, Goat anti-mouse (IgG) polyclonal antibody. Test region, Mouse monoclonal anti-HCG antibody. A labeled antibody: Colloidal gold conjugate of monoclonal anti-HCG antibody B.

[Storage Conditions & Period of Validity]

1. Store at 4°C~30°C, and it is valid for 36 months.
2. The test kit should be kept away from direct sunlight, moisture and heat.
3. After opening the foil bag, the product should be used within 1 hour.

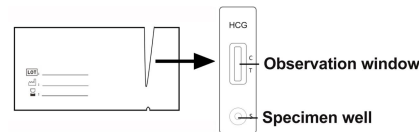
[Specimen Collection and Preparation]

Urine samples at any time of the day can be used for pregnancy testing.

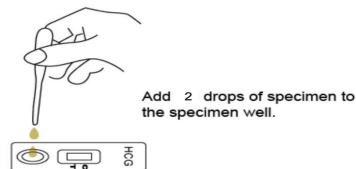
Samples should be collected in a clean, dry glass or plastic container without any special pre-treatment. If specimen cannot be assayed immediately, it can be stored at 8-30°C for up to 4 hours prior to testing, or refrigerated at 2-8°C for 24 hours.

[Test Procedure]

Allow the test device and the specimen to equilibrate to room temperature (15- 30°C) prior to testing.



1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test device from the pouch and use it as soon as possible.

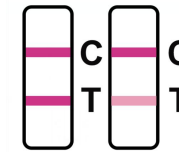


2. Lay the device flat on table. Pinch the bulb at the upper end of the dropper, place the lower end in the urine, and then slowly loosen the bulb. Hold the dropper vertically to add 2 full drops of urine to specimen well "S" as arrow indicated.

3. Wait for red line(s) to appear. The test results should be read in approximately 3-5 minutes. Do not interpret results after 5 minutes.

[Interpretation of test results]

Positive result:



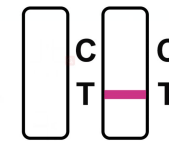
Two distinct red lines appear in the control region (C) and test regions (T). The color intensity of the test line (line T) may vary since different stages of pregnancy have different concentrations of HCG hormone.

Negative result:



Only one red line appears in the control region (C). No apparent line in the test region (T).

Invalid result:



No coloured line appears in the control region (C), the test should be invalid since an improper test procedure may have been performed or deterioration of reagents may have occurred. Repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[Quality Control]

A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume.

[Limitations of inspection methods]

1. Uterine tumor, hydatidiform mole or climacteric patient, because of high hCG content in urine, it may have positive results.
2. End of gestation because of natural or unnatural reasons which include natural childbirth, cesarean section, habitual abortion or medical abortion, the urine sample may be tested positive in continuous weeks.

- There is the possibility that this test device may produce false results. Consult your physician before making any medical decisions.
- This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

[Performance Characteristics]

Limit of detection

The limit of detection of the HCG Pregnancy Test is 10mIU/ml.

Specificity

The hLH (500 mIU/mL), hFSH (1000 mIU/mL), hTSH (1000 µIU/mL), hematuria (Hb concentration of 1.8 g/L), bilirubinuria (85 µmol/L), proteinuria (5.65 mmol/L), Ascorbic Acid (0.2 mg/mL), caffeine (0.2 mg/mL), glucose (20 mg/mL), urine specific gravity (1.008~1.030) and urine pH (3.0~9.0) did not affect the test results of the HCG Pregnancy Test (Colloidal Gold).

Repeatability

Samples of different concentrations of HCG standards were tested separately using the same lot of kit, each concentration was tested 10 times. All test results of 25 mIU/ml, and 10 mIU/ml of HCG standards is positive, and all test results of 5 mIU/ml of HCG standards is negative.

Hook effect

There was no hook effect when the concentration of HCG is up to 200000 mIU/mL.

HAMA (human anti-mouse antibody) interference

20ng/mL HAMA has no effect on the detection results of the test device.

Diagnostic specificity and sensitivity

A clinical evaluation was carried out on 118 clinical samples from women of childbearing age, compared the results obtained using the HCG Pregnancy Test (Colloidal Gold) with a commercially available HCG Pregnancy Test.

Clinical Accuracy of HCG Pregnancy Test (Colloidal Gold):

	Reference		Total
	Positive (+)	Negative (-)	
Positive (+)	63	1	64
Negative (-)	0	54	54
Total	63	55	118

Positive agreement (Sensitivity):>99.9%

Negative agreement (Specificity):98.18%

Total consistency rate (Accuracy):99.15%

[References]

- Johnson, S. R., Godbert, S., et. al., Accuracy of a home-based device for

giving an early estimate of pregnancy duration compared with reference methods, Fertil Steril. 2013 Dec; 100(6):1635-41

- Larsen, J., Buchanan, P., et. al., Human chorionic gonadotropin as a measure of pregnancy duration, Int J Gynaecol Obstet. 2013 Dec; 123(3):189-95
- Greene, D. N., Grenache, D. G., Pathology consultation on human chorionic gonadotropin testing for pregnancy assessment, Am J Clin Pathol. 2015 Dec; 144(6):830-6
- Kennedy, C. E., Yeh, P. T., et. al., Self-testing for pregnancy: a systematic review and meta-analysis, BMJ Open. 2022 Feb 28;12(2):e054120
- Gnoth, C., Johnson, S., Strips of Hope: Accuracy of Home Pregnancy Tests and New Developments, Geburtshilfe Frauenheilkd. 2014 Jul; 74(7): 661-669

[Instruction of Symbols]

	CE Marking with NB Identification		Batch number
	Consult instructions for use		In vitro diagnostic medical device
	Do not re-use		Date of manufacture
	Storage temperature		Contains sufficient for <n> tests
	Manufacturer		Use before the date
	Authorized Representative in European Community		Keep dry
	Keep away from sunlight		Do not use if package is damaged and consult instructions for use
	Catalogue number		Unique device identifier

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4 pcs/box	HCG1UST-4
5 pcs/box	HCG1UST-5
10 pcs/box	HCG1UST-10
20 pcs/box	HCG1UST-20
25 pcs/box	HCG1UST-25
40 pcs/box	HCG1UST-40
50 pcs/box	HCG1UST-50
100 pcs/box	HCG1UST-100

Revision Date:2024-11-20

Specification	REF
1 pc/box	HCG1UST-1
2 pcs/box	HCG1UST-2
3 pcs/box	HCG1UST-3