cyclotest®
Ich bin mir sicher.

Instructions cyclotest® Pregnancy Test

(Midstream)

UEBE

Intended use

cyclotest® Pregnancy Test is a self-performing immunoassay designed for the qualitative determination of humanchorionicgonadotropin (hCG) in urine for early detection of pregnancy by visual.

cyclotest® Pregnancy Test is designed for both professional and lay users.

⚠ Safety instructions

In-vitro diagnostic aid for self-testing

- Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
- Do not use beyond the labeled expiration date.
- Do not reuse the test devices. Discard it in the dustbin after single use.
- Do not use if pouch is damaged or opened.
- Do not touch the membrane on the strip.
- Once the pouch is opened, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
- Treat urine samples and used devices as if they are potentially infectious. Avoid contact with skin.
- Make sure you have a urine sample cup before beginning (not included).

Materials provided

Each box contains:

- One foil pouch, contains one test stick and one desiccant (do not eat).
- Instructions for Use

Other equipment or reagents needed but not provided

- A clean and dry container
- Timer

When to begin testing

The test could be used from the first date of missed menstruation. In most cases the test is accurate at this date. However, because of variation in hCG concentration among women, or potential miscalculation of the last period, if there is a negative result, and pregnancy is still suspected, you should retest after a few days.

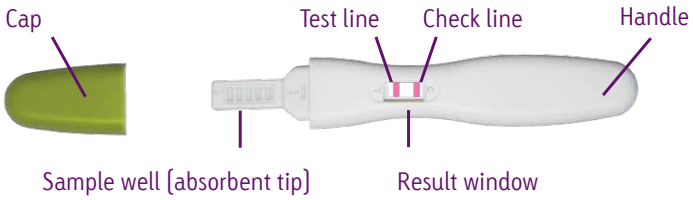
Performing the test

Specimen collection and handling

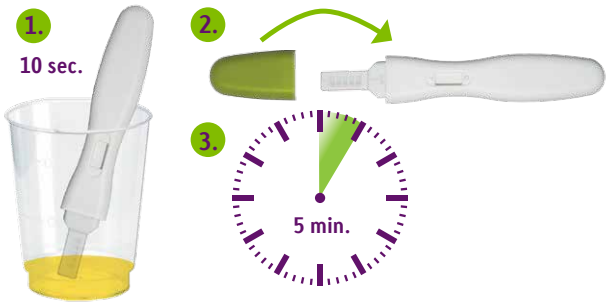
1. Urine specimen must be collected in a clean and dry container.
2. First morning urine specimen is preferred due to its high concentration of hCG. However, urine specimens collected at any time of the day may be used. If specimens cannot be assayed immediately, they can be stored at 2-8 °C for up 72 hours prior to testing.
3. Urine specimens exhibiting visible precipitates should be settled to obtain a clear specimen for testing.

Assay procedure

1. Bring the test pouch and urine to room temperature. To begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch and use it as soon as opened.
2. Hold the handle of the test with one hand. Use the other hand to remove the cap and expose the absorbent tip. Put the cap aside for re-cap later (See the picture).



3. Collect your urine into a clean container (not provided) and dip the absorbent pad into the urine for at least 10 seconds. You can also point the absorbent tip downward and place it in urine stream for at least 10 seconds until it is thoroughly wet.



4. Re-cap the device and wait for colored bands to appear. Read the result at 5 minutes.
5. Depending on the concentration of hCG in the test specimen, positive results may be observed in as short as 40 seconds. However, to confirm negative results, the complete reaction time (5 minutes) is required. So read the result within 5 minutes.
6. Discard the test device after single use in the dustbin.

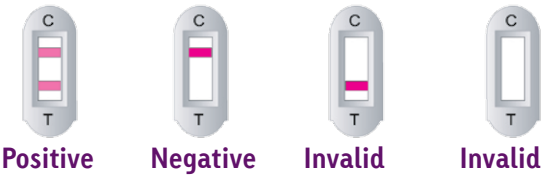
Do not read results after 10 minutes.

Interpretation of result

Positive: Two distinct color bands appear - one on the control and one on the test region. This indicates that pregnancy has been detected. The color intensity of the test bands may vary as the hormone concentration changes during pregnancy.Early precautions are important. Consult your doctor and your midwife immediately in order to safeguard your health and that of your baby. Avoid potential risks to the embryo (e.g. X-rays).

Negative: Only one color band appears on the control line and no band appears on the test region. This means there is no pregnancy detected.

Invalid: There are no visible bands at all, or if one red band appears only on the test region. If this happens, repeat a new test. If the test still fails, please contact the distributor with the lot number.



Quality control

Built in Quality Control Features

In addition, a built procedural control is being used designated as control region (C) on the test device to indicate sufficient sample volume was added.

Summary and Explanation

Human Chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. During normal pregnancy, hCG can be detected in urine as early as 7 days following conception, doubling every 1.3 to 2 days. At the time of the last missed menstrual period, urine hCG levels are about 100mIU/ml with peak levels of 100,000 to 200,000mIU/ml seen at the end of the first trimester. The presence of hCG soon after conception and its subsequent increase in concentration during early gestational growth make it an ideal marker for the early detection of pregnancy.

Mode of operation

The cyclotest® Pregnancy Test is a rapid one-step test, based on an immunochromatographic technology. A membrane with an absorbent pad overlaps a strip of fiber glass paper that is impregnated with lyophilized colloidal conjugate of gold particles and monoclonal solid phase antibodies to hCG. Another absorbent pad at the endof the assay absorbs excess sample fluid. The urine sample is introduced into the device, and proceeds through the absorbent pad, then laterally onto a chromatographic membrane. As it contacts the membrane, the sample dissolves the lyophilized conjugate. In a reactive sample, the hCG antigen will bind to the antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti-hCG monoclonal antibody affixed on the test zone („T“) will bind the HCG-gold conjugate complex, forming a pink line („T“). All samples will cause a pink colored line in the control zone („C“). This lined is formed by the binding of the polyclonal antibodies (Anti-mouse lgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates sample amount is appropriate and the test has been carried out correctly. In less than 5 minutes, levels of hCG as low as 25mIU/ml can be detected.

Reagents

Test device comprised colloidal gold coated with anti ß-hCG monoclonal antibody; NC membrane coated with anti ⍰-hCG monoclonal antibody and rabbit anti mouse IgG polyclonal antibodies.

Information for professional use

Testing of quality control material to verify the performance of the test is recommended for each new lot of test. In addition, users should follow their state and local regulations and guidelines regarding GLP requirements.

Qualitiy control material. Commercial control material or fresh samples from known pregnant and non-pregnant patients may be used with each lot as controls to verify the performance of the test. We recommend using control materials with hCG concentrations known to be near (above and below) the clinical cutoff.

Interpretation of the symbols

	Consult instructions for use		Do not reuse
	Temperature limitation		Use by
	Manufacturer		Contains sufficient for ‹n› tests
	Keep dry	IVD	In vitro diagnostic medical device
	Caution, see safety instructions	REF	Catalogue number
	Keep away from sunlight	LOT	Batch code
	Do not use if package is damaged		
CE 0123	This test complies with Council Directive 98/79/EC of 1998 on in-vitro diagnostics and bears the CE 0123 mark (TÜV SÜD Product Service GmbH).		

Reference

- Chard T. Pregnancy tests: a review. Hum Reprod. 1992 May; 7 (5): 701-10. Review
- American Pregnancy Association. Human Chorionic Gonadotropin (HCG): The Pregnancyc Hormone.
- Womens health Research. Dept. of OB/GNY, University of New Mexico. HCG Reference Service. http://www.hcglab.com/hCG%20levels.htm
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- Henry JB. Clinical Diagnosis and Management by Laboratory Methods, 18th edition, 1991, WB Saunders and Co.
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- Engvall, E. Method in Enzymology, 1980, 70:419.

Performance characteristics

1. Sensitivity

cyclotest® Pregnancy Test will display positive results with specimens containing hCG at the level close to or greater than 25 mIU/ml.

2. Specificity

The following compounds exhibited no interference when dissolved in urine, which had hCG levels of 0 and 25 mIU/ml.

Non-cross reacting homologous hormones

HFSH	1000 mIU/ml	(WHO 1st IS)
HLH	500 mIU/ml	(WHO 1st IRP)
HTSH	1000 µIU/ml	(WHO 2nd IRP)

3. Accuracy

Comparison studies on the cyclotest® Pregnancy Test with a legally marketed device were performed in various clinical reference laboratory. Positive and negative resultes were compared and the correlation was ›99.9%

Clinical Accuracy of the cyclotest® Pregnancy Test

	Reference method (Positive)	Reference method (Negative)	Total
cyclotest® Pregnancy Test (positive)	411	0	411
cyclotest® Pregnancy Test (negative)	0	309	309
Total	411	309	720

Diagnostic Sensitivity (Positive agreement) =411/ (411+0) =100% Diagnostic Sensitivity (Negative agreement) =309/ (309+0) = 100%

4. Non-cross reacting compounds:

Acetaminophen	20 mg/dl
Acetosal	20 mg/dl
Salicylic Acid	20 mg/dl
Asorbic Acid	20 mg/dl
Caffeine	20 mg/dl
Gentisic	20 mg/dl
Thiophene	20 mg/dl
Ampicillin	20 mg/dl

Tetracycline	20 mg/dl
Hemoglobin	20 mg/dl
Albumin	1000 mg/dl
Glucose	20 mg/dl
Ketone	20 mg/dl
Bilirubin	20 mg/dl
Theelol	20 mg/dl
Pregnanedione	20 mg/dl

5. Repeatability and Reproducibility

Three lots of cyclotest® Pregnancy Test were used and 10 strips of each lot tested in HCG standard solution with different concentrations prepared at 0 mIU/ml, 25 mIU/ml and 100 mIU/ml.

hCG concentration	Lot 1		Lot 2		Lot 3		Variability
	P	N	P	N	P	N	
0 mIU/ml	0	10	0	10	0	10	%0
25 mIU/ml	10	0	10	0	10	0	%0
100 mIU/ml	10	0	10	0	10	0	%0

P: Positive N: Negative

All samples were positive at and beyond the cut-off level. No different results were observed.

Limitation of the procedure

- Alcohol may interfere with test result. It is not recommended using the test after drinking.
- Occasionally specimens containing less than 25 mIU/ml for urine also yield positive results.
- A very early pregnancy containing an extremely low concentration of hCG can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
- HCG levels may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion or therapeutic abortion.
- In cases where very high levels of hCG are present (›500,000 mIU/ml) a false negative result can occur due to a „Prozone“ effect. If pregnancy is still suspected, simply dilute specimen 1:1 with deionized water and retest.
- If a urine sample is too dilute (i.e.: low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, a first morning urine sample should be obtained and retested 48 hours later.
- As is true with any diagnostic procedure, the user should evaluate data obtained by the use of this kit in light of other clinical information and consult to the physicians for the final diagnosis of pregnancy before make any decision of medical relevance.

Storage and stability

The test kit can be stored at normal temperature (4 °C to 30 °C, or 39 °F to 86 °F) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat. Do not freeze.

cyclotest® service hotline

Ensure you read our notes on using the cyclotest® Pregnancy Test carefully and familiarised yourself with its features.

If you have any further questions, you can call our cyclotest® service hotline, which is open from Mondays to Thursdays from 8.00 am to 5.00 pm and on Fridays until 4.30 pm.

Your team of cyclotest® advisers is looking forward to taking your call.

For customers from Germany:

cyclotest® service hotline
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www.cyclotest.de

For customers from Switzerland:

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