THE CYCLOTEST® SERVICE HOTLINE

You have undoubtedly read our instructions on the use of the cyclotest® pregnancy test carefully and have familiarised yourself with its characteristics. If you have any additional questions, you can call our cyclotest® service hotline, which is available Monday to Thursday from 8:00am to 5:00pm and Fridays until 4:30pm. Your cyclotest® advisory team looks forward to speaking with you.

Service
+49 (0) 93 42 / 92 40 40
www.cyclotest.de

For customers from Switzerland:
Service
0 52 224 41 47
www.cyclotest.ch

Pregnant and you need to keep it a secret?
Anonymous advice is available here:
Tel.: 0800 40 40 020 www.geburt-vertraulich.de.
A service provided by the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth for pregnant women in need.

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EXPLANATION OF SYMBOLS

- Consult the instructions for use
- Indication of the storage temperature limit values
- Manufacturer
- Keep dry
- Note the safety instructions
- Protect against heat and direct sunlight
- Not suitable for re-use
- Expiry date
- Contents sufficient for <n> tests
- IVD In vitro diagnostic device
- REF Article number
- LOT Batch number
- Do not use if the packaging has been opened or damaged

CE 0123 This test corresponds to Directive 98/79/EC of the Council of 1998 on in vitro diagnostics and bears the mark CE 0123 (TÜV SÜD Product Service GmbH).

Bibliographic references

- Chard T. Pregnancy tests: a review. Hum Reprod. 1992 May; 7 (5): 701-10. Review
- American Pregnancy Association. Human Chorionic Gonadotropin (HCG): The Pregnancy Hormone.
- Women's Health Research. Dept. of OB/GNY, University of New Mexico. HCG Reference Service.
- Chayen J, Daly JR, Loveridge N. The cytochemical bioassay of hormones. Recent Prog. Horm. Res. 1976; 32:33-72.
- Henry JB. Clinical Diagnosis and Management by Laboratory Methods, 18th edition, 1991, WB Saunders and Co.
- Wide L, Gemzell CA. An immunological pregnancy test. Acta Endocrinology 1960; 35:261.
- Cart, K.J. J. Clin. Endocrinol. Metab., 1975,40 :537
- Braustein, G. D. Am J. Obstet. Gynecol., 1976,126:678
- Batzer, F.R. Fertility & Sterility, 1980, 34:1.
- Engvall, E. Method in Enzymology, 1980, 70:419.

PERFORMANCE CHARACTERISTICS

1. Sensitivity
cyclotest® pregnancy indicates positive results for samples that exhibit an hCG level of approximately 25 mIU/ml or above.

2. Precision
The following components resulted in no impairment of the result when dissolved in urine.

Homologous hormones without cross reaction
HFSH 1000 mIU/ml (WHO 2nd IS)
HLH 500 mIU/ml (WHO 2nd IRP)
HTSH 1000 µIU/ml (WHO 2nd IRP)

3. Accuracy
Comparative studies between cyclotest® pregnancy test and authorised laboratory devices have been performed in various clinical reference laboratories. The positive and negative results were compared, resulting in a concordance of > 99.9%.

Clinical accuracy of the cyclotest® pregnancy test

	Reference procedure (positive)	Reference procedure (negative)	Total
cyclotest® pregnancy test (positive)	349	0	349
cyclotest® pregnancy test (negative)	0	671	671
Total	349	671	1020

Diagnostic sensitivity (positive concordance): 349/349 x 100% = 100%
Diagnostic accuracy (negative concordance): 671/671 x 100% = 100%
Total concordance: 1020/1020 x 100% = 100%

4. Components without cross reaction

Paracetamol	20 mg/dl	Tetracycline	20 mg/dl
Aspirin	20 mg/dl	Haemoglobin	20 mg/dl
Salicylic acid	20 mg/dl	Albumin	1000 mg/dl
Ascorbic acid	20 mg/dl	Glucose	20 mg/dl
Caffeine	20 mg/dl	Ketone	20 mg/dl
Gentisic acid	20 mg/dl	Bilirubin	20 mg/dl
Thiophene	20 mg/dl	Theelol	20 mg/dl
Ampicillin	20 mg/dl	Pregnanedione	20 mg/dl

5. Repeatability and reproducibility

Three batches of the cyclotest® pregnancy test were used. For each batch, 10 test sticks were tested in an hCG standard solution with different concentrations (0 mIU/ml, 25 mIU/ml and 100 mIU/ml).

hCG concentration	Batch 1		Batch 2		Batch 3		Deviation
	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 the cut-off level and above it. No deviating results were detected.

LIMITATIONS OF THE TEST PROCEDURE

- Alcohol may influence the test result. It is recommended that the test not be used following alcohol consumption.
- In individual cases, samples that contain a concentration of less than 25 mIU/ml in the urine may show positive results.
- In the very early stage of a pregnancy, a negative result may appear due to the low hCG concentration. In this case, a second sample should be taken and tested at least 48 hours later.
- hCG concentrations may still be detectable in the urine for several weeks after a natural birth, a caesarean section, a miscarriage or an induced abortion.
- In cases of very high hCG concentrations (> 500,000 mIU/ml), a false negative result may occur due to a "prozone effect". If a pregnancy is suspected nevertheless, the sample should simply be diluted with deionised water in a 1:10 ratio and the test should be repeated.
- If a urine sample is too diluted (i.e. the specific density is too low), it might not contain a meaningful hCG concentration. If a pregnancy is suspected nevertheless, a sample should be taken from the first urine in the morning 48 hours later and the test should be repeated.
- As with any other diagnostic procedure, the data obtained using this diagnostic should be assessed with consideration of additional clinical data. For the final determination of a pregnancy a doctor should be consulted before any decisions with medical significance are made.

STORAGE AND SHELF LIFE

The test can be stored at room temperature (between 4°C and 30°C) in the sealed foil pouch until the expiration date. Avoid direct sunlight, moisture and heat. Protect against freezing.

Pregnancy test
Instructions for use
(midstream test)

UEBE

INTENDED USE

cyclotest® pregnancy test is a self-running immunological test for the qualitative determination of human chorionic gonadotropin (hCG) in the urine for early detection of a pregnancy.
cyclotest® pregnancy test can be used either professionally or at home.

⚠ SAFETY INSTRUCTIONS

In vitro diagnostic device for self-testing
- Read through the instructions for use carefully before performing the test. Pay attention to the position of the C and the T line.
- Do not use the test after the printed expiry date.
- Do not reuse the test. Dispose of the test in household waste after one-time use.
- Do not use the test if the foil pouch is damaged or has been opened.
- Do not touch the membrane on the test stick.
- Use an adequate amount of midstream urine.
- Use the test immediately after tearing open the foil pouch. Longer contact with air moisture can damage the product.

- Handle urine samples and used tests like potentially infectious objects. Avoid contact with the skin.
- To perform the test, have a urine beaker (not included) ready so that you can submerge up to half of the absorbent tip.
- Make sure that no urine reaches the result window.

TEST COMPONENTS

Contents of the package:
- One foil pouch containing a test stick and a desiccant (not suitable for human consumption).
- Instructions for use

You will also need (not included):
- A clean, dry container
- A clock

DETERMINING THE BEGINNING OF THE TEST

The test can be used from the first day of a missed period. At this time, the test will show a correct result in most cases. However, because the hCG concentration may differ from one woman to another and because the possibility exists that the time of the last menstruation was not calculated correctly, the test should be repeated after a few days if the result is negative but a pregnancy is still suspected.

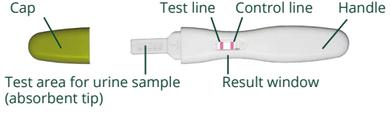
PERFORMING THE TEST

Collecting the urine sample and performing the test

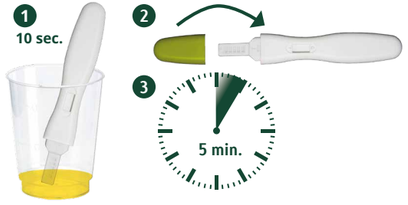
- The urine sample should be collected in a clean, dry container.
- You can use the test at any time of day, but the first urine in the morning is preferred because the concentration of the hormone hCG is highest in the morning urine. If the test cannot be performed immediately after urine collection, the sample can be stored for up to 72 hours at 2–8°C.
- If the urine sample contains visible particles, these should first be allowed to settle so that a clear sample can be used to perform the test.

Test procedure

- The foil pouch and the urine should be at room temperature. At the beginning of the test, tear open the foil pouch using the tear notch and remove the test stick. Use the test stick immediately after opening the foil pouch.
- Hold the handle of the test stick with one hand. Remove the cap with the other hand and expose the absorbent tip. Set the cap aside for later use. (See illustration)



- Collect your **midstream urine** (time at the middle of urination) in a clean container (not included). Immerse half of the absorbent tip in the urine for at least 10 seconds. You can also hold the test stick with the absorbent tip downwards in the urine stream for at least 10 seconds.



- Replace the cap and wait until the coloured lines appear. The test result can be read after 5 minutes.
- Depending on the hCG concentration in a sample, positive results may appear after as little as 40 seconds. However, for confirmation of a negative result it is important to wait for the entire reaction time (5 minutes). Therefore the result should only be read after 5 minutes.
- Dispose of the test stick in household waste after one-time use.

After 10 minutes the test must no longer be evaluated.

EVALUATING THE RESULT

Positive: Two coloured lines appear — one control line and one test line (see illustration). This result indicates that a pregnancy has been detected. Since the hormone concentration changes during pregnancy, the colour intensity of the test line may vary. **Even a weakly coloured test line indicates a positive result.** Early prenatal care is important. Contact your doctor and a midwife immediately to protect your health and your baby's health. Avoid potential risks to the embryo (e.g. X-rays).

Negative: Only the control line appears; no test line is indicated. This result means that no pregnancy could be detected.

Invalid: No lines or only a coloured test line appears. In this case repeat the test with a new test stick. If an invalid result is indicated again, please contact the retailer and specify the batch number.

QUALITY CONTROL

Integrated control function
The test has an integrated control function The control line (C) indicates whether an adequate amount of sample liquid has been used.

FOR YOUR INFORMATION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone that is emitted from the developing placenta shortly after fertilisation. In the event of a normal pregnancy, hCG may already be detectable in the urine 7 days after conception, with the concentration doubling every 1.3 to 2 days. At the time of the missed period, the hCG value in the urine is approx. 100 mIU/ml. At the end of the first trimester of a pregnancy, peak values of 100,000 to 200,000 mIU/ml are measured. Since hCG appears shortly after conception and because of its subsequent increase in concentration early in the pregnancy, the hormone is particularly well suited for early detection of a pregnancy.

HOW IT WORKS

cyclotest® pregnancy test is a rapid test based on immunochromatographic technology. A membrane with an absorbent layer lies over a rigid fibreglass paper that has been soaked with a lyophilised colloidal gold conjugate with monoclonal solid phase antibodies to hCG. An additional absorbent covering on the end of the test area absorbs excess sample fluid. The urine sample is placed on the test strips, flows through the absorbent layer and laterally reaches a chromatographic membrane. When it comes into contact with the membrane, the sample dissolves the lyophilised conjugate. In a responsive sample, the hCG antigen binds to the antibodies in the colloidal solution. During the forward movement of the conjugate on the membrane, the monoclonal antibodies to hCG that were applied in the test range ("T") bind to the hCG gold conjugate complex and a purple line appears ("T"). A purple line appears on the control area ("C") for all samples. This line

appears due to the binding of the polyclonal antibodies (anti-mouse IgG) applied in the control area to the colloidal gold conjugate of the sample. This line indicates that an appropriate amount of sample liquid was present and that the test was performed correctly. An hCG concentration of only 25 mIU/ml can be detected in the urine in less than 5 minutes.

REAGENTS

Test stick with colloidal gold conjugate with anti-ß-hCG monoclonal antibodies; NC membrane with anti-α-hCG monoclonal antibodies and rabbit anti-mouse IgG polyclonal antibodies.

INFORMATION FOR PROFESSIONAL USE

For every new batch of test sticks, it is recommended that a test be performed with control material to check the performance of the test. Furthermore, the users should adhere to the international guidelines of the GLP principles.

Material for quality control: The test performance can be checked for every batch using commercially available control material or fresh samples from pregnant or non-pregnant patients. We recommend using control materials with verified hCG concentrations in the approximate range of the clinical cut-off value (just below it and just above it).