Nano Repro

Product Portfolio

IN VITRO DIAGNOSTICS

Home-Tests

Tests for professional use

German manufacturer

NOTES

HOME-TESTS
FAMILY PLANNING LINE
FertiQUICK©
OvuQUICK©
VagiQUICK©
GraviQUICK©
GraviQUICK© (Early)
MenoQUICK©
PREVENTIVE HEALTHCARE LINE
GlutenCHECK©
Heli-C-CHECK©
FerritinCHECK©
FOBCHECK©
TSH CHECK©
Alkohol TEST©
Drug TEST©
ALLERGY LINE
AllergoCHECK©
MilkCHECK©

FOR PROFESSIONAL USE ONLY
Troponin I
D-Dimer
Strep A
Influenza A/B
Microalbumin Dipstick

NOTES

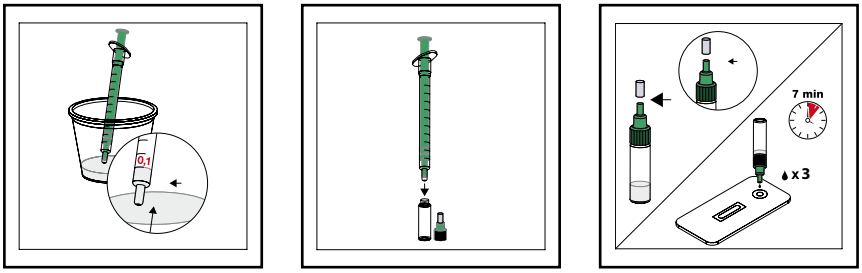
FAMILY PLANNING LINE

FAMILY PLANNING LINE
FertiQUICK©
OvuQUICK©
VagiQUICK©
GraviQUICK©
GraviQUICK© (Early)
MenoQUICK©

FertiQUICK©

FertiQUICK© is a rapid test for use at home to detect the concentration of sperm in semen with 95.1% accuracy.

The self-test shows whether the sperm count is considered within normal limits (at least 20 million sperm/ml). Other fertility factors are not detected by the test.
Test cassette method with an antigen-antibody principle (immunoassay) is used. The test results can be read through the appearance of a line in the test field. The package contains all the necessary items needed for the test: a test cassette in a sealed pouch, a solution bottle, a semen transfer syringe, a semen collection cup and detailed instructions for use.



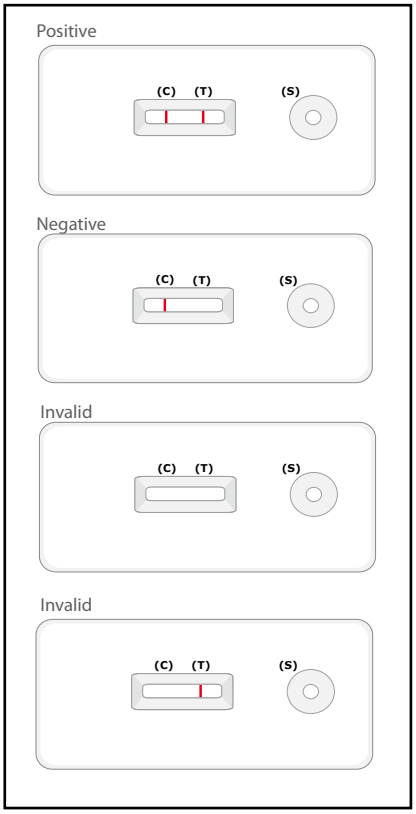
Test performance

- Collect the semen sample in the semen collection cup and let it stand for until semen sample becomes liquefied and can be easily transferred.
- Draw the sample into the semen transfer syringe and add the entire semen sample (0,1ml) to the solution bottle.
- Mix the content of the solution bottle and let the solution bottle stand for 2 minutes to create the semen mixture.
- Open the foil pouch and remove the test cassette.
- Hold the bottle with the semen mixture straight up and down over the test cassette and squeeze gently to add exactly 3 drops to the sample well (S). Please note, that there should be no liquid applied to the result windows marked with the letters (T) and (C).
- Please wait exactly 7 minutes after adding 3 drops to the sample well. Then read the result.

Background

"Infertility is not just a woman's concern. A problem with the male is the sole cause, or a contributing cause, of infertility in about 40 percent of infertile couples. About one-fourth of infertile couples have more than one cause or factor related to their inability to conceive. About 10 to 15 percent of couples have no identifiable cause for their infertility after medical investigation" (Men´s Health, University Health Care).

http://web.archive.org/web/20070704064049/http://healthcare.utah.edu/healthinfo/adult/men/infertil.htm



Interpretation of the test results

To read the test results simply determine whether a line is present or absent at the Control (C) position. It does not matter how strong or weak a Control line (C) is.
Positive: if there are two lines both in the Control (C) position and the Test (T) position, the test result is positive. The positive result means that the sperm count is at least 20 million sperm per milliliter and the sperm count level is considered normal to father a child.
Negative: if there is only Control line (C) and NO Test line (T), the test result is negative. The sperm count is less than 20 million per milliliter. However, a negative test result alone does not prove infertility.
Invalid: if there is no Control line (C) in the result window, the test did not run correctly and the results are not valid.

OvuQUICK©

OvuQUICK© is a rapid test for use at home to detect the qualitative luteinizing hormone (LH) surge in the urine with >99.9% accuracy. Therefore, the test predicts that the ovulation will take place in the next 24-36 hours.

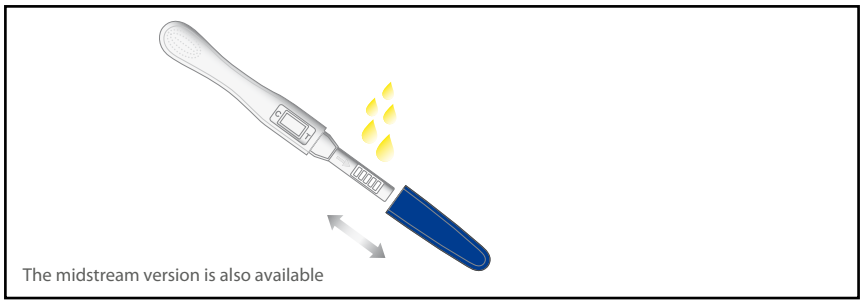
OvuQUICK© uses a combination of antibodies that contain a monoclonal LH antibody in order to detect increased hormone levels exceeding 25 mIU/mL LH.

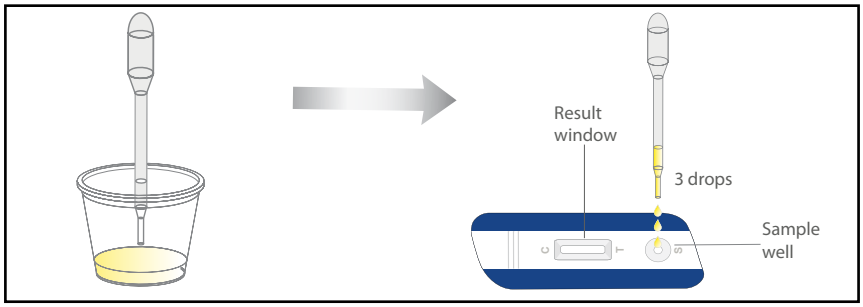
Advantages of OvuQUICK©

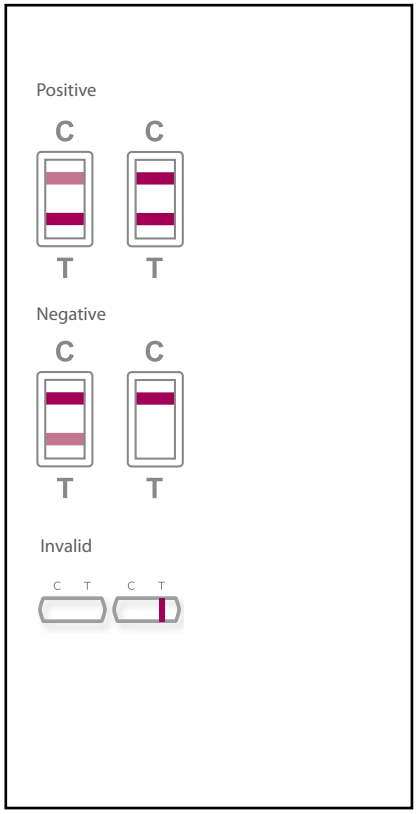
It is possible to determine the fertile days with the help of different tests: testing stripes, test sticks and test cassettes. The ovulation test OvuQUICK© works by means of the cassette technique, which is also used by doctors and other professionals in order to determine the ovulation as precise as possible.

Test performance (test cassette)

- Gather urine in a clean and dry container.
- Remove the protective foil from the test cassette and use it as soon as possible.
- Put 3 drops of urine in the sample well of the test cassette and watch the time.
- Read results after 3-5 minutes.







Interpretation of the test results

Positive: two coloured lines appear and the Test line (T) has the same intensity or is darker compared to the Control line (C). This indicates that your ovulation is probably due within the next 24-36 hours.
Negative: two lines are visible, but the Test line (T) is lighter than the Control line (C) or there is no Test line. This indicates that there was no LH surge and you should continue daily testing.
Invalid: the Control line fails to appear. Review the procedure and perform the test again with a new test cassette.

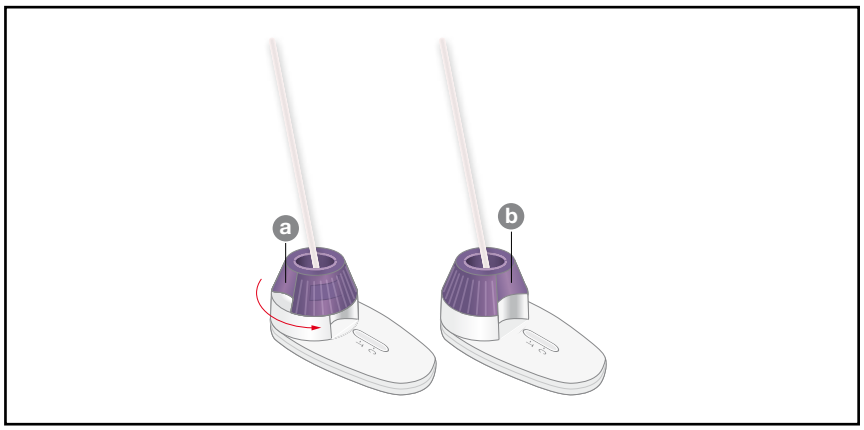
Background

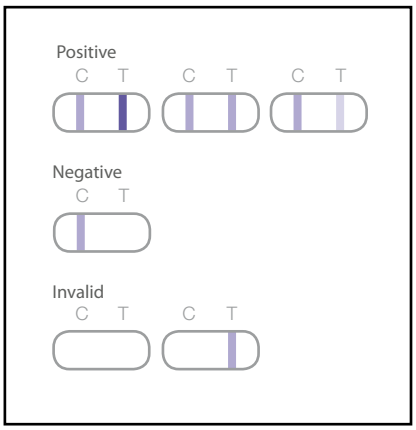
In Germany 15% of all couples are infertile (Bruckert, 1991), 3-4% of them remain childless for the rest of their lives (Templeton et. al., 1991). A woman has four or five fertile days in each cycle/month and the ovulation takes place in this period. The ovulation test OvuQUICK© helps women to detect the fertile days – optimal timing to get pregnant. This is an important factor for family planning.

VagiQUICK©

VagiQUICK© is a qualitative rapid diagnostic test designed to detect Candida antigens in the vaginal secretion sample with 90.0% accuracy.

With the help of VagiQUICK© women can quickly and easily find out if they have a vaginal yeast infection. Test cassette method with an antigen-antibody principle (immunoassay) is used.
The test results can be read through the appearance of a line in the test field. The package contains all the necessary items needed for the test: a test cassette, a bag with desiccant, a smear swab and detailed instructions for use. The test results can be read after 10 minutes.





Test performance

- Take the test cassette from the package and place it on a plain surface.
- Remove the aluminum cover.
- Take a vaginal secret specimen with the swab.
- Insert the swab in the liquid of the purple sealing cover, stir for 20 seconds and then take it out.
- Turn the sealing cover first in the direction of the arrow (a) and then turn it back in the initial position (b).
- You can read the result after 10 minutes.

Background

"Vulvovaginal candidiasis (VVC) is an insidious infection that afflicts a large proportion of women of all ages, and 5 to 8% of affected women experience recurrent VVC (RVVC)" (Zhou et. al., 2009).

http://iai.asm.org/content/77/9/4130.full

Symptoms: pruritus vulvae, vulval soreness; white, "cheesy" discharge, the discharge is non-offensive, foul-smelling or purulent discharge suggests bacterial infection; dyspareunia (superficial); dysuria (external).

http://patient.info/doctor/vaginal-and-vulval-candidiasis

Interpretation of the test results

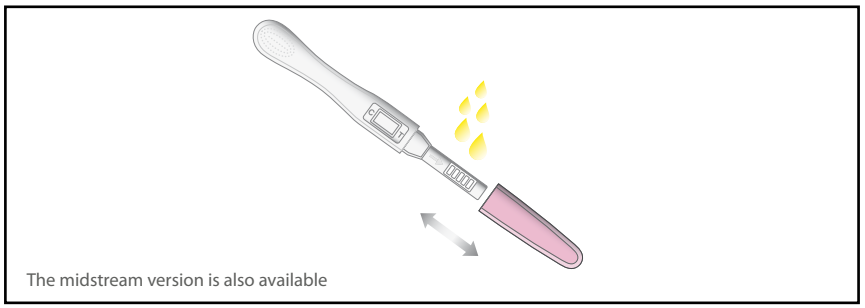
The test is valid only when a blue line appears in the C - marked field. The differences in color intensity are not relevant for the interpretation of the test results.
Positive: the test result is positive when blue lines appear both in the T and C fields. In this case, a Candida infection is detected.
Negative: if only a Control line (C) is visible in the result window with no Test line (T), the test result is negative.
Invalid: if there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.

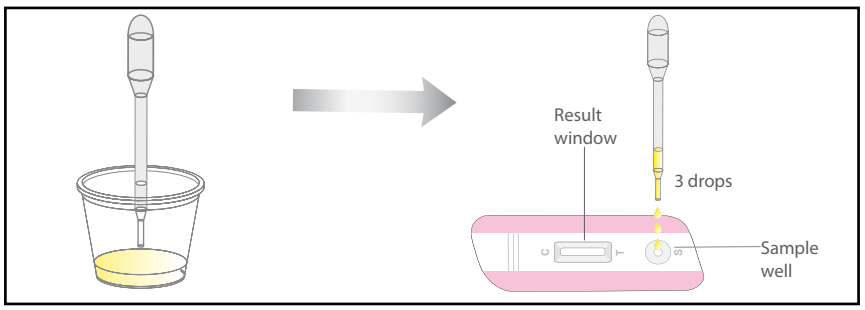
GraviQUICK©

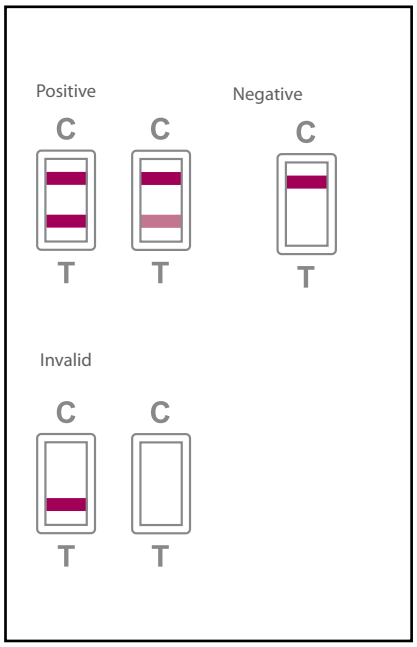
GraviQUICK© is a home-test to determine a pregnancy with the hCG level of 25 mIU/ml as early as the first day of a missing period. GraviQUICK® is > 99.9% accurate.

GraviQUICK© (Early)

GraviQUICK© (Early) is a home-test to detect the presence of hCG in urine before missed period (from the 10th day after conception) with more than 99.9 % accuracy: hCG values in the urine are measured.







Test performance (test cassette)

The tests can be performed at any time of the day. However, the first morning urine is advised to be used for testing as it contains the highest concentration of hCG pregnancy hormone.

- Open the sealed pouch and remove the test device. Lay it face up on a clean, dry and flat surface.
- Hold the pipette with the urine sample straight up and down over the test cassette and squeeze gently to add exactly 3 drops to the sample well. Please note, that there should be no liquid applied to the result windows marked with the letters (T) and (C).
- Please wait 3-5 minutes after adding 3 drops to the sample well. Then read the result.

Background

Home pregnancy tests determine the presence of hCG pregnancy hormone in a sample of urine. hCG level doubles approximately every two days and GraviQUICK© (Early) can detect it in urine as early as 10 days following conception. GraviQUICK© and GraviQUICK© (Early) have similar results to the pregnancy tests done on urine in most doctors' offices if they are used exactly as instructed.

Interpretation of the test results

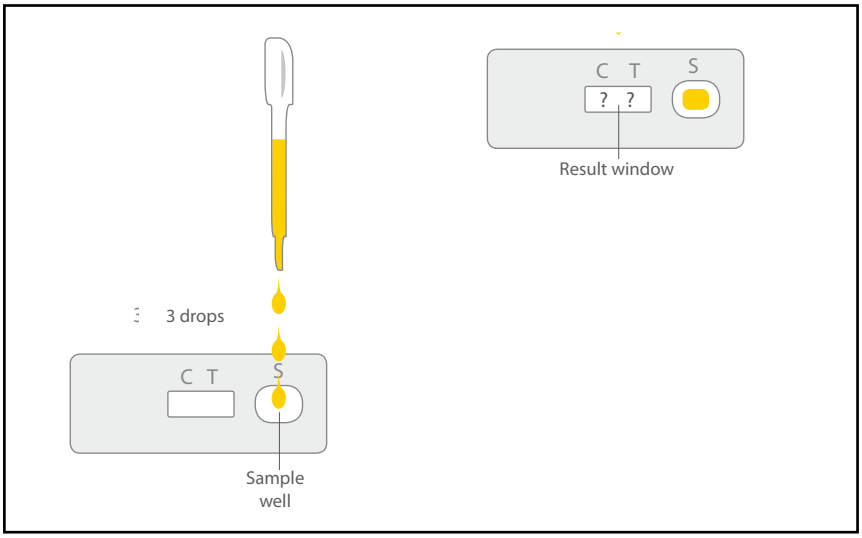
To read the test results simply determine whether a line is present or absent at the control (C) position. It is not important how strong or weak the Control line (C) is.

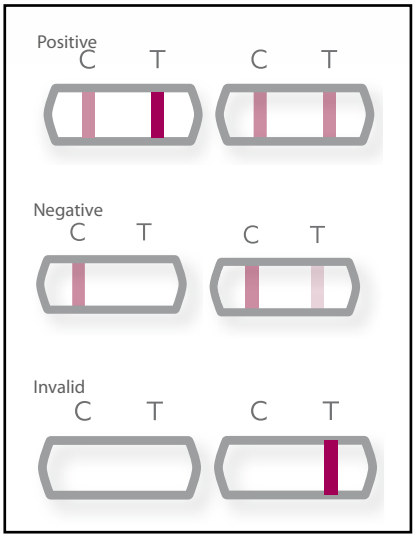
Positive: if a Control line (C) is visible in the result window along with a Test line (T), the test result is positive.
Negative: if only a Control line (C) is visible in the result window with no Test line (T), the test result is negative.
Invalid: if there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.

MenoQUICK©

MenoQUICK© is a qualitative test for home use to detect the status of menopause with 99.9% accuracy.

The test measures the concentration of the Follicle Stimulating Hormone (FSH) in the urine and indicates whether or not a woman has entered her menopause. This knowledge is of special interest for women, as it gives them the possibility to discuss hormone treatment and to evaluate the risk of osteoporosis with their gynecologist.





Test performance

To perfom the test, the first morning urine should be used as it contains the highest concentration of hormones and provides the most accurate results.
If a woman still has a period, the test should be performed during the first week of menstrual cycle (2-7 days after the first day of the last menstruation). The second test should be performed one week later.
If a menstrual cycle is not regular, the first test should be performed at any time of the month and the second test one week later.

Background

"The typical "mature woman" is aged 40 years or older and has completed childbearing. During their late 40s, most women enter the menopausal transition. This period of physiologic change is due to ovarian senescence and estrogen decline and is usually completed between ages 51 and 56. Menopause marks a defining point in this transition. Specifically, menopause is defined by the World Health Organization as the point in time of permanent menstruation cessation due to loss of ovarian function. Clinically, the menopause refers to a point in time that follows 1 year after menstruation cessation.
With ovarian senescence, declining hormone levels have specific effects on many tissues. Some effects lead to physical complaints, such as vasomotor symptoms and vaginal dryness, whereas others are metabolic and structural changes. These include osteopenia, osteoporosis, skin thinning, fatty replacement of the breast, cardiovascular changes, and genitourinary atrophy. As a result, postmenopausal women have specific issues associated with aging and estrogen loss that may negatively affect their individual health" (Hoffman et. al., 2012).

http://accessmedicine.mhmedical.com/content.aspx?sectionid=41722311&bookid=399&jumpsectionID=41727768&Resultclick=2

MenoQUICK© detects the level of FSH to prove whether or not a woman has entered perimenopause. If a woman knows that she has already entered perimenopause, she has the possibility to take the necessary steps to keep her body healthy and to avoid risks involved in menopause (e.g. osteoporosis, rising blood pressure, cholesterol).

Interpretation of the test results

Positive: two faint red to dark red lines (Control line (C) and Test line (T)) are visible in the result window. For a positive result the colour of the Test line (T) has to be as dark as or darker than the Control line (C).
Negative: the Control line (C) appears in the result window, and the Test line (T) is either less intensive than the Control line (C) or does not appear at all.
Invalid: if there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.

NOTES

NOTES

PREVENTIVE HEALTHCARE LINE

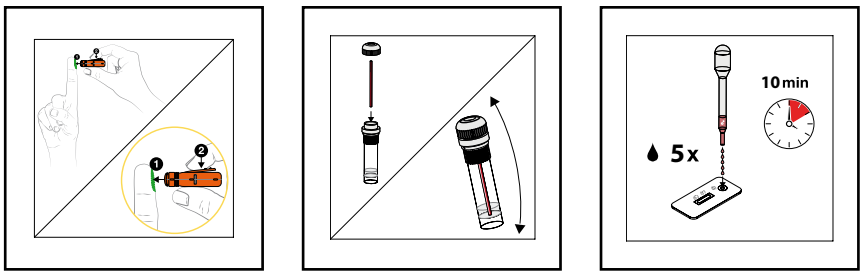
PREVENTIVE HEALTHCARE LINE
GlutenCHECK©
Heli-C-CHECK©
FerritinCHECK©
FOBCHECK©
TSH CHECK©
Alkohol TEST©
Drug TEST©

GlutenCHECK©

GlutenCHECK© is a rapid test for use at home to detect the presence of anti IgA tissue transglutaminase antibodies (a-tTG-IgA) in whole blood.

GlutenCHECK© is suitable for both, as an aid in the diagnosis of gluten intolerance as well as a therapy follow-up. a-tTG-IgA antibody level should fall when gluten is removed from the diet. After 6 months on gluten-free diet the antibodies will often become undetectable.
The test result must be confirmed by a physician with further recommendation to maintain a gluten-free diet.

Each kit contains everything necessary for the test performance: a test cassette, an instruction leaflet, a solution bottle with sample dilution buffer, 1 automatic sterile lancet for comfortable blood sampling, a glass capillary tube, a pipette, an alcohol pad and a plaster. The results can be read within 10 minutes.

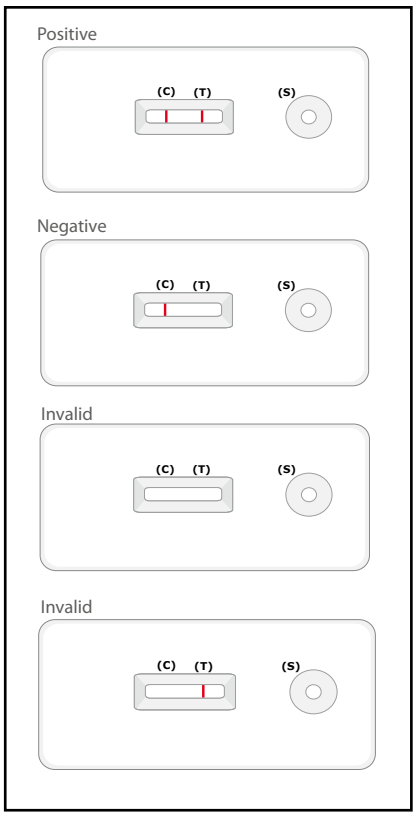


Test performance

- Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two times again.
- Press the automatic lancing device with the round opening firmly against the clean fingertip (1) and activate it by pushing the button (2).
- Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally in the blood drop until it has completely filled.
- Insert the filled glass capillary into the solution bottle and mix the content of the solution bottle.
- Insert the pipette into the solution bottle and add a few drops of the sample mixture.
- Add exactly 5 drops to the sample well (S).
- Please wait 10 minutes after adding 5 drops to the sample well. Then read the result.

Background

The gluten intolerance (celiac disease), known as a sprue in adults, is an autoimmune disorder of the small intestine, when the immune system attacks the body's own tissues. The common symptoms of gluten intolerance include bloating and diarrhea, caused by a reaction to a gluten protein found in many foods. The following symptoms could also be a sign of gluten intolerance, such as weight loss, malnutrition and skin disorders.



Interpretation of the test results

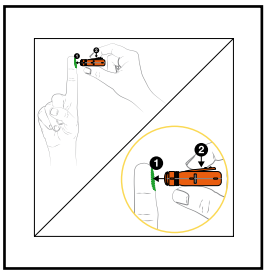
Positive: If a faint red to dark red Control line (C) is visible in the result window along with a faint red to dark red Test line (T), the test result is positive.
The test result indicates that the blood sample contains gluten intolerance specific IgA antibodies, indicating with a high probability existing gluten intolerance.
Negative: If only a faint red to dark red Control line (C) is visible in the result window with no Test line (T), the test result is negative.
The test result indicates that gluten intolerance specific IgA antibodies are not present in the blood sample. No gluten intolerance has been detected.
Invalid: if there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.

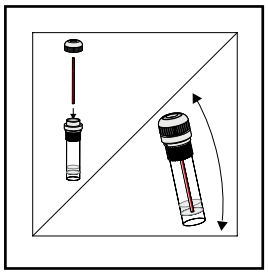
Heli-C-CHECK©

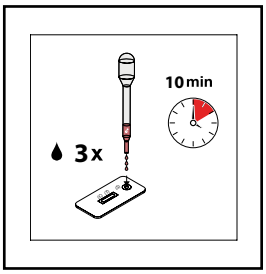
Heli-C-CHECK© is a rapid test for use at home to detect the presence of *Helicobacter pylori* antibodies in whole blood.

Heli-C-CHECK© is intended as an aid in the diagnosis of *Helicobacter pylori* infection. The test result must be confirmed by the physician.

Each kit contains everything necessary for the test performance: a test cassette, an instruction leaflet, a solution bottle with sample dilution buffer, 1 automatic sterile lancet for comfortable blood sampling, a glass capillary tube, a pipette, an alcohol pad and a plaster. The results can be read after 10 minutes.





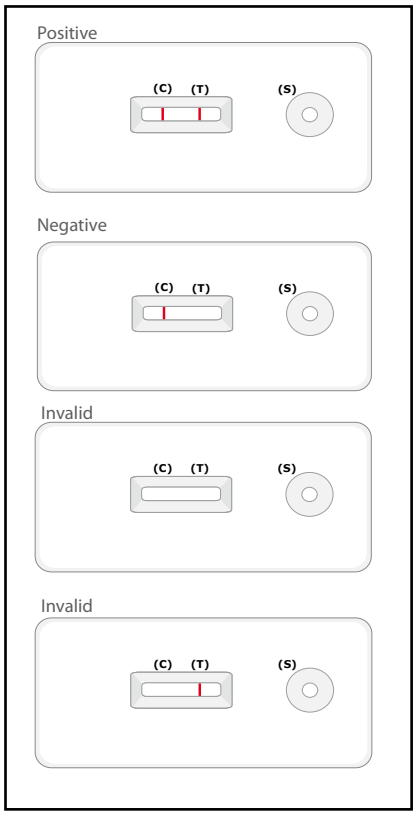


Test performance

- Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two times again.
- Press the automatic lancing device with the round opening firmly against the clean fingertip (1) and activate it by pushing the button (2).
- Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally in the blood drop until it has completely filled.
- Insert the filled glass capillary into the solution bottle and mix the content of the solution bottle.
- Insert the pipette into the solution bottle and draw up a few drops of the sample mixture.
- Add exactly 3 drops to the sample well (S).
- Please wait 10 minutes after adding 3 drops to the sample well. Then read the result.

Background

The most common cause of painful inflammation of the stomach lining with nausea and abdominal discomfort is a bacterium called *Helicobacter pylori*. Chronic inflammation in the stomach (gastritis) or ulcer may have further consequences. *Helicobacter pylori* bacteria can contribute to the development of diseases, such as ulcers in the stomach and lymphoma progress (a type of cancer).



Interpretation of the test results

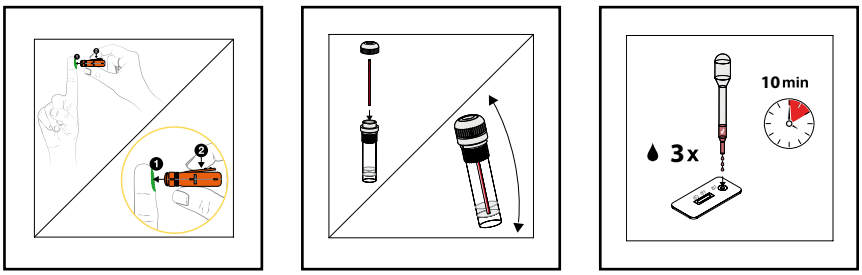
To read the test results simply determine whether a line is present or absent at the control (C) position.
Positive: if a Control line (C) is visible along with a Test line (T), the test result is positive: blood sample contains *Helicobacter pylori* specific IgG antibodies, indicating an existing or recent infection with ***Helicobacter pylori***.
Negative: if only a Control line (C) is visible with no Test line (T), the test result is negative: ***Helicobacter pylori*** specific IgG antibodies are not present in the blood sample.
Invalid: if there is no Control line (C) or only a Test line (T), the test did not run correctly and the results are not valid.

FerritinCHECK©

FerritinCHECK© is a rapid test for the detection of iron deficiency at home.

Iron deficiency is caused by insufficient dietary intake and absorption of iron, or iron loss from bleeding (for example, menstrual bleeding, abnormal bleeding or ulcers), also during pregnancy or growth phase, and has serious health consequences. FerritinCHECK© is intended as an aid in the diagnosis of iron deficiency. The final diagnosis must be confirmed by a physician.

Each kit contains everything necessary for the test performance: a test cassette, an instruction leaflet, a solution bottle with sample dilution buffer, 1 automatic sterile lancet for comfortable blood sampling, a glass capillary tube, a pipette, an alcohol pad and a plaster. The results can be read after 10 minutes.

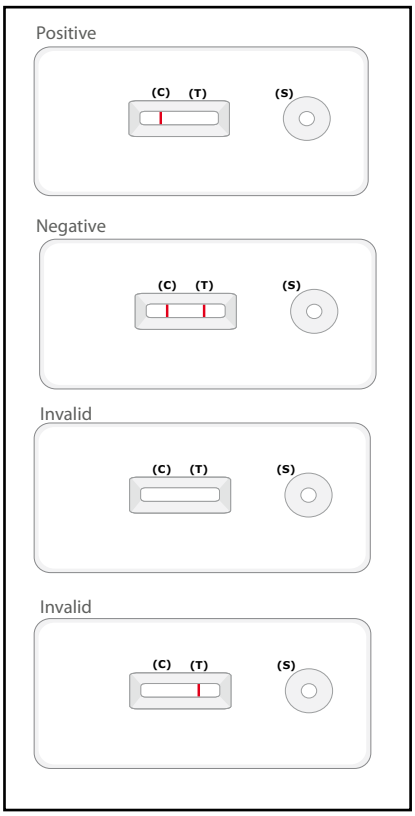


Test performance

- Twist the grey cap on the automatic lancet until cap separates easily from lancet body. Then twist it at least two times again.
- Press the automatic lancing device with the round opening firmly against the clean fingertip (1) and activate it by pushing the button (2).
- Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally in the blood drop until it has completely filled.
- Insert the filled glass capillary into the solution bottle and mix the content of the solution bottle.
- Insert the pipette into the solution bottle and draw up a few drops of the sample mixture.
- Add exactly 3 drops to the sample well (S).
- Please wait 10 minutes after adding 3 drops to the sample well. Then read the result.

Background

Iron deficiency prevalence is highest among young children and women of childbearing age. It is important that current body iron stores are sufficient. Iron is stored in a protein complex called ferritin. Hence, ferritin in the human blood serum is a laboratory marker of the total amount of iron stored in the body.
Fatigue, headache, pallor, strong heartbeats or shortness of breath are all possible indications of an iron deficiency.



Interpretation of the test results

Positive: if there is only Control line (C) and NO Test line (T), the test result is positive: the iron concentration in the blood is low; iron reserve is inadequate.
Negative: If a faint red to dark red Test line (T) is visible in the result window along with a Control line (C) the rest result is negative. The iron concentration in the blood is considered normal and there is no iron deficiency.
Invalid: if there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.

FOBCHECK©

FOBCHECK© is a rapid one-step test for the qualitative detection of human hemoglobin in fecal samples.

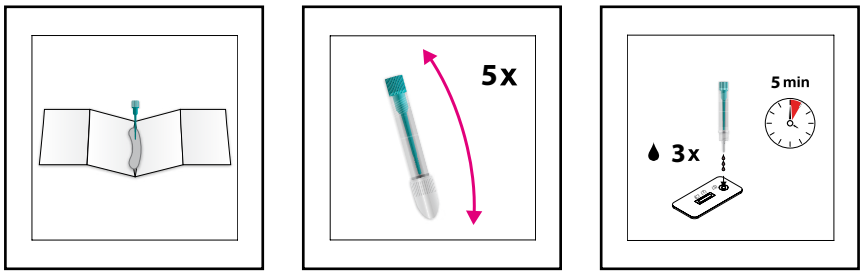
FOBCHECK© is designed to help diagnose gastrointestinal disorders and detects human hemoglobin (Hb) with a cut-off level of 40 ng/ml.

In addition to possible intestinal diseases such as diverticulitis, colitis, or colon polyps, the blood in the stool sample may indicate an early stage of the colorectal cancer.

Advantages

- Rapid screening for early detection
- Minimal sample contact
- Easy to use
- Detects human occult blood as low as 40 ng/ml hemoglobin as the threshold level
- No cross reactivity to hemoglobin from other species
- Results are accurate and reliable:
  - ✓ Sensitivity of 97.1 %
  - ✓ Specificity of 98.0%
  - ✓ Accuracy of 98.6%

Each kit contains everything necessary for the test performance: a test cassette, an instruction leaflet, a sampling tube with developer solution and sample transfer device. The results can be read within 5 minutes.



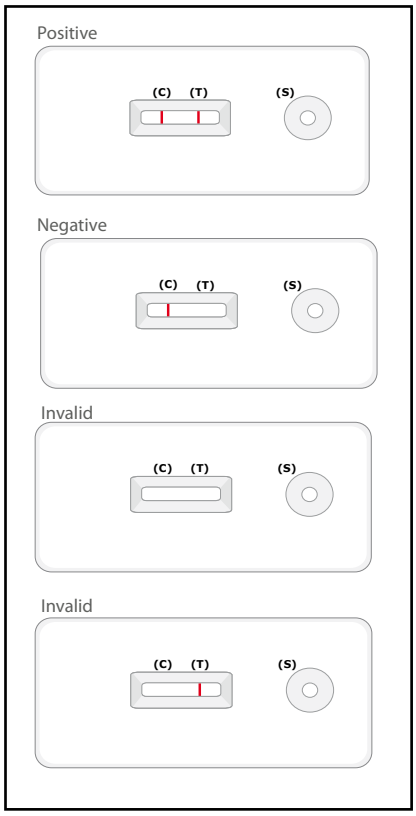
Test performance

- A stool specimen should be collected into the sampling tube containing developer solution.
- After mixing the stool sample, dispense 3 drops of solution into the sample well on the test cassette.
- Read the test result after 5 minutes.

Background

"Colorectal cancer is the third most common cancer in the world, with nearly 1,4 million new cases diagnosed in 2012. 2,4 million cases of colorectal cancer diagnosed annually worldwide by 2035." *(http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics)* Colorectal cancer mortality can be reduced if cases are detected and treated early. The hidden blood is not seen with the naked eye and can be detected with FOB screening test.

Symptoms: abdomen persistent pain, blood in the stool, a change in bowl habits, diarrhea, constipation.



Interpretation of the test results

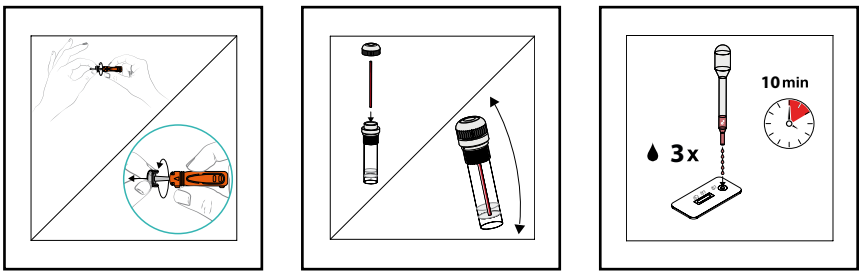
A red band opposite the (C) symbol indicates the test has worked correctly.
Positive: If a faint red to dark red Control line (C) is visible in the result window along with a faint red to dark red Test line (T), the test result is positive.
Negative: the test result is negative if a red line appears in the (C) marked field, and no line appears in the (T) field.
Invalid: the test result is invalid if the control line (C) is not visible within 5 minutes. The test failed or the test procedure was not followed properly.

TSH CHECK©

TSH CHECK© assesses the presence of elevated thyroid-stimulating hormone TSH, >5 µIU/mL levels in a whole blood sample.

The thyroid plays a central role in the control of the metabolism. Malfunctions can therewith influence the whole body. To detect hyper-or hypofunctions, TSH is a reliable indicator. TSH gets secreted by the pituitary gland and stimulates the thyroid to produce the hormones T3 and T4.
Whenever the concentration of the thyroid hormones T3 and T4 drops, TSH levels rise.

Each kit contains everything necessary for the test performance: a test cassette, an instruction leaflet, a solution bottle with sample dilution buffer, 1 automatic sterile lancet for comfortable blood sampling, a glass capillary tube, a pipette, an alcohol pad and a plaster. The results can be read after 10 minutes.

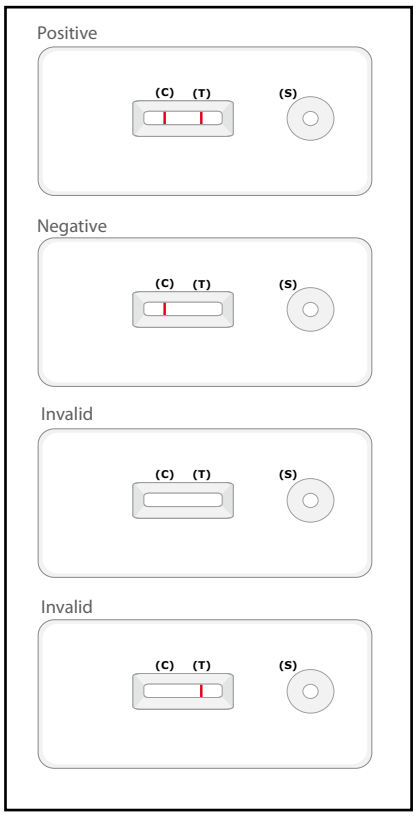


Test performance

- Twist the grey cap on the automatic lancet until cap separates easily from the lancet body. Then twist it at least two more times.
- Press the automatic lancing device with the round opening firmly against the clean fingertip (1) and activate it by pushing the button (2).
- Press a drop of blood out of the fingertip. Hold the glass capillary tube horizontally in the blood drop until it has completely filled.
- Insert the filled glass capillary into the solution bottle and mix the content of the solution bottle.
- Insert the pipette into the solution bottle and add a few drops of the sample mixture.
- Add exactly 3 drops to the sample well (S).
- Please wait 10 minutes after adding 3 drops to the sample well. Then read the result.

Background

The symptoms of a thyroid hypofunction include, amongst others, fatigue, listlessness, feeling of coldness, constipation, muscle cramps or weight gain.
TSH CHECK© assesses whether TSH levels are elevated. A normal TSH concentration ranges from 0.4 µIU/ml to 4.5 µIU/ml while a value of >5 µIU/ml indicates a thyroid hypofunction. If the test shows a positive result, one can assume that the TSH concentration is above normal values indicating a thyroid hypofunction. The definitive diagnosis should be confirmed by a physician.



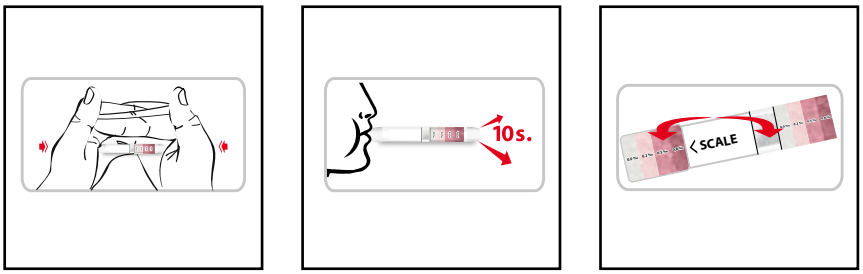
Interpretation of the test results

Positive: If a faint red to dark red control line (C) is visible in the result window along with a faint red to dark red test line (T), the test result is positive. This result indicates a TSH concentration in your blood sample of more than 5 µIU/ml.
Negative: If a faint red to dark red control line (C) but no faint red to dark red test line (T) is visible in the result window, the test result is negative. This result indicates a TSH concentration in your blood sample of less than 5 µIU/ml.
Invalid: If there is no control line (C) or only a test line (T) visible in the result window, the results are not valid.

Alkohol TEST©

Alkohol TEST© is a disposable breathalyzer used to measure the concentration of alcohol in the exhaled breath. Alkohol TEST© detects the presence of alcohol as low as 0,2‰* of blood alcohol concentration (BAC), and distinguishes low levels of alcohol from levels in excess of 0,1 mg/l in the exhaled breath. Already 0,2‰ BAC impairs driving skills and increase the risk of being involved in a crash.

Alkohol TEST© contains a glass tube filled with active substance in the adsorption granules form, filters, foil and 2 protection caps.



Test performance

- Wait 15 minutes after last alcohol consumption and do not smoke before performing the test.
- Push the two ends of the tube by pressing strongly to pierce the protective foil on both sides of the tube.
- Take a deep breath and blow into the mouthpiece of the test following the arrows on the tube in a continuous breath 2 times for 10 seconds. Do not inhale while blowing into the detector. Make sure air is coming out from the other side of the tube. The crystals inside the tube become warm. If this does not happen, go back to the step 2.
- Read results at 2 minutes by identifying the color of the crystals to determine the relative BAC. Do not read results after 5 minutes.

Background

BAC level rises during an hour after last alcohol consumption. BAC will also depend on a number of other factors including: sex, age, physical condition, amount of food or drugs consumed, type of alcohol as well as many other factors. Alkohol TEST© is designed for personal use only and should be taken as a warning that the subject may have detectable alcohol in their system. It is not the official BAC measurement test. A positive result should be confirmed by an evidentiary alcohol test.

***** Alkohol TEST© detects the presence of alcohol at the 0,2‰, 0,5‰ and 0,8‰ BAC levels.

Interpretation of the test results

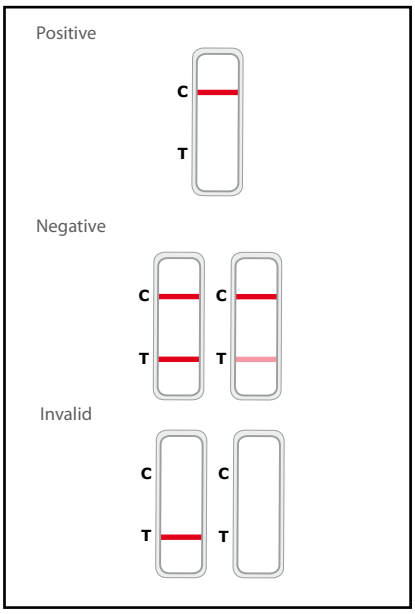
White crystals inside the tube will change color in the presence of alcohol in the exhaled breath. The relative BAC results may be read by comparing with the color scale on the tube or packaging. Please note that the color change may have different intensity. Some white areas may still remain even though the presence of alcohol is shown on the test.

Alkohol Test:
- *is NOT a medical product (medical rapid test)*
- *does NOT give the results to be used in court*

DrugTEST©

Drug TEST© is a rapid test for use at home to detect 6 types of drugs and their metabolites in urine:
Amphetamine, Benzodiazepine, Cocaine, Marijuana, Methadone,Opiates/morphine.
DrugTEST©can detect the following substance classes simultaneously and thus provides information which drugs were consumed. The test is calibrated to detect the individual substances from the listed concentration levels (cut-off):

Analyte	Sample	Run time	Sensitivity	Specificity	Trueness	Accuracy	Cut-off level (ng/ml)
Amphetamine Benzodiazepine Cocaine Marijuana Methadone Opiates	Urine	5 minutes	98.50 %	n.a.	n.a.	n.a.	1000 300 300 50 300 300



Test performance

- Collect urine in a clean container
- Open the foil pouch and perform the test immediately.
- Remove the cap of the test cassette and dip the strips vertically into the urine up to the marking for at least 10 seconds. Be sure to dip the test cassette only to the lower edge and do not touch the result window or spill urine on the window.
- Re-cap the test cassette, place it on a flat surface and wait for the colored bands to appear.

Read the result after 5 minutes. Do not read the result after more than 10 minutes.

Background

Drugs of abuse mostly are highly potent psychotropic substances and preparations derived from these. Generally, these drugs show a mind-altering effect accompanied by a change of perception. Drug abuse entails various risks and can lead to health-associated or psychosocial issues in the long term.
Target audience are parents willing to check their children, young people travelling the world and visiting various parties as well as consumers of the respective drugs. The consumption of some food products might result in false-positive results (e.g. the consumption of a large amount of poppy seed products can give a positive result for opiates). For a quantitative confirmation of the result further specific analysis methods are necessary. A medical assessment by a qualified professional is necessary for every patient to confirm drug abuse.

Interpretation of the test results

Positive: If a light-to-dark red Control line (C) is visible in the result window along with NO red line in the test region (T) the test result is positive.
The concentration of the drugs (or their derivatives) is above the cut-offlevel which indicates drug abuse.
Negative: The test result is negative if a light-to-dark red Control line (C) is visiblein the result window along with a light-to-dark red line in the test region (T). Here the concentration of the drugs (or their derivatives) in the sample is below the cut-off level of the test.
Invalid: The result is invalid when no control line (C) or only a test line (T) isvisible.

NOTES

NOTES

ALLERGY LINE

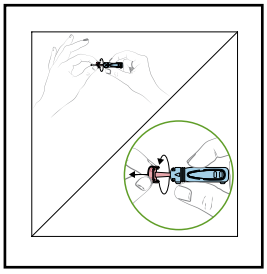
ALLERGY LINE
AllergoCHECK©
MilkCHECK©

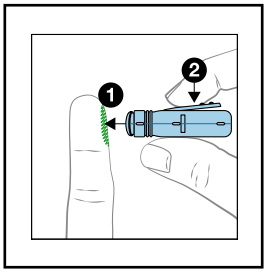
AllergoCHECK©

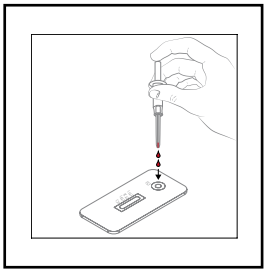
AllergoCHECK© is a rapid test for the detection of allergy antibodies to cat hair, grass pollen and house dust mite.

With AllergoCHECK© you can quickly and easily determine at home if you have increased susceptibility to allergy.

The test is designed to detect IgE antibodies in the blood. Each kit contains everything necessary for the test performance: an instruction leaflet, a sterile finger lancet, a blood tube, a developer solution and a test cassette. The result can be read after 10 minutes.







Test performance

- Press the finger lancet against the soft pad of your finger tip.
- Collect the blood drop with the tube.
- Add the blood to the test cassette and then add the developer solution.
- Read the definitive test result after 10 minutes.

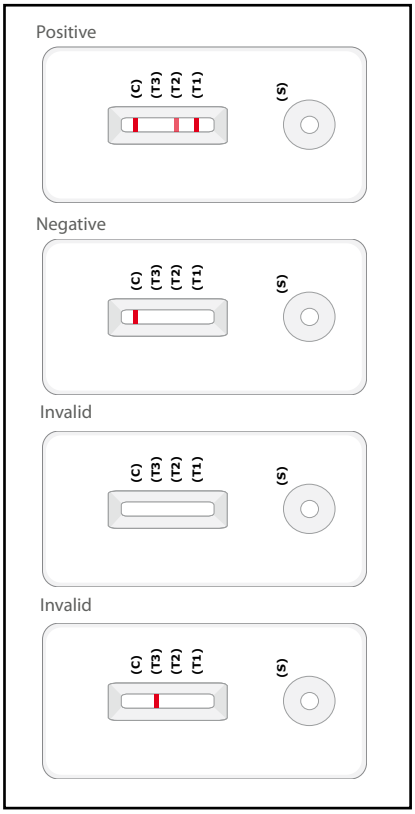
Background

Sneezing, runny nose, itchy eyes are not always the symptoms of a cold. Often it is an allergic reaction to something in the air. There are three most common airborne allergens, such as cat hair, dust mite and grass pollen. Worldwide, airborne dust causes the most problems for people with allergies.

Symptoms: sneezing, runny nose, itchy eyes and ears, severe wheezing, coughing, shortness of breath, sinus problems.

Results

T1: Allergy to cats
T2: Allergy to dust mite
T3: Allergy to grass pollen



Interpretation of the test results

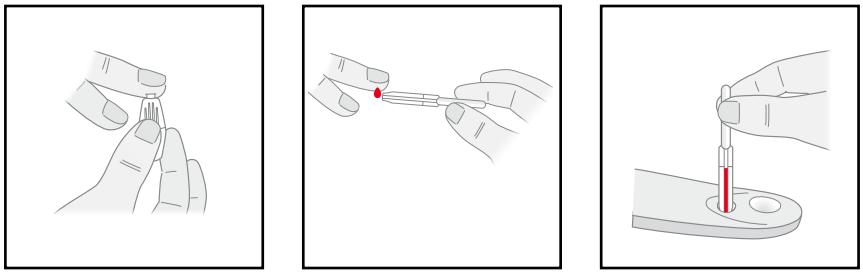
A pink or red band opposite the C symbol indicates the test has worked correctly. **Positive:** If a faint red to dark red Control line (C) is visible along with one or more faint red to dark red Test line/lines (T), the result is positive.Test lines indicates that high levels of IgE allergy antibodies have been detected and you may have a sensitivity to that particularallergen.
A positive result is significant only when it is accompanied with allergy symptoms.
Negative: the test result is negative if a red line appears in the (C) marked field, and no line appears in the (T) field. This means that there are no high levels of allergy antibodies.
Invalid: if there is no Control line (C) or only (a) Test line(s) (T), the test did not run correctly and the results are not valid.

MilkCHECK©

MilkCHECK© is a rapid test to detect allergy antibodies to cow's milk protein.

The test detects raised levels of IgE allergy antibodies against cow's milk protein and works in a similar way to hospital laboratory testing. Determining whether you have a cow's milk allergy is the first step to improving your quality of life by avoiding milk proteins.

Each kit contains everything necessary for the test performance: an instruction leaflet, a sterile finger lancet, a blood tube, a developer solution and a test cassette. The positive result can be read after 30 minutes.



Test performance

- Press the finger lancet against the soft pad of your finger tip.
- Collect the blood drop with the tube.
- Add the blood to the test cassette and then add the developer solution.
- Read the definitive test result after 30 minutes.

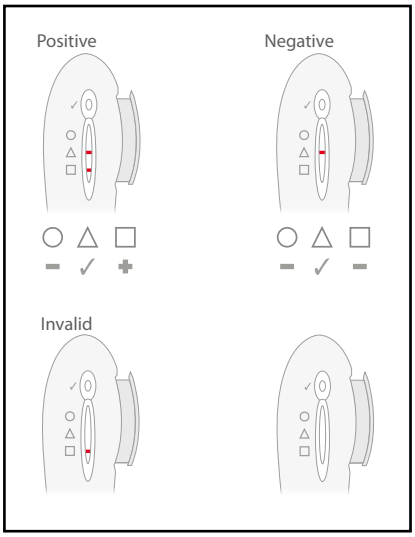
Background

"Milk allergy should not be confused with lactose intolerance. A food allergy is an overreaction of the immune system to a specific food protein. A food allergy can be potentially fatal. Unlike food allergies, food intolerances do not involve the immune system. Lactose-intolerant people are unable to digest specific foods, and may experience symptoms such as nausea, cramps, gas, bloating and diarrhea. While lactose intolerance can cause great discomfort, it is not life-threatening."

(https://www.foodallergy.org/allergens/milk-allergy)

The most common food allergy in children is cows' milk allergy. To prevent an allergic reaction, strict avoidance of cow's milk and cow's milk products is essential.

Symptoms: itching, swelling lips and face, coughing, shortness of breath and wheezing, asthma, dry, itchy throat and tongue, itchy skin, rashes and eczema, diarrhea, vomiting.



Interpretation of the test results

Pink or red line opposite the △ symbol indicates the test has worked correctly.
No line should be visible opposite the ○ symbol.
A pink or red line opposite the □ symbol (irrespective of the intensity) indicates that high levels of IgE allergy antibodies have been detected and you may have a sensitivity to that specific allergy.
It is essential that you have or have had at some time at the past symptoms for a positive result to be significant. Even a faint line opposite the □ symbol should be recorded as a positive result.

NOTES

For professional use only

For professional use only
Troponin I
D-Dimer
Strep A
Influenza A/B
Microalbumin

Troponin I

Troponin I is a rapid one-step chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in whole blood, serum or plasma with 99.3% accuracy. Troponin I test is a qualitative, membrane based immunoassay for the detection of cTnI in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI). The Troponin I cut-off-level is 1 µg/mL.

Each kit contains: 20 Troponin I test devices, 20 disposable pipettes, buffer solution (20 ampules), 1 package insert.
Material required but not provided: tubes for collection of blood samples, lancets (only for whole blood from fingertip), centrifuge (for plasma/serum), heparinised capillaries and dispensary bulb (for whole blood from fingertip) and a timer.

Test performance

- Collect whole blood from fingertip.
- Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface.

Serum or plasma

- Hold the provided pipette vertically and transfer 3 drops of serum or plasma (ca. 75 µl) into the round specimen well (S) of the Troponin I test.
- Start the timer.

Venipuncture whole blood

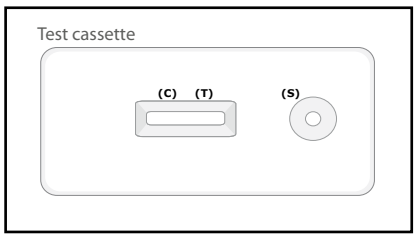
- Hold the provided pipette vertically and transfer 2 drops (ca. 50 µl) of whole blood into the round specimen well (S) of the Troponin I test.
- Add 1 drop of the provided buffer solution.
- Start the timer.

Fingertip whole blood

- Transfer 2 hanging drops (50 µl) of whole blood from the fingertip puncture into the round specimen well (S) of the Troponin I test.
- Add 1 drop of the provided buffer solution.
- Start the timer.
- Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not read results after more than 20 minutes.

Background

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three sub-unit complex consisting of Troponin I, T and C. Along with tropomyosin, this structural complex forms the main component that regulates the calciumsensitive ATPase activity of actomyosin in skeletal and cardiac muscles. After cardiac injury occurs, cTnI is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, cTnI levels remain elevated for 6-10 days, thus providing a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma. cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina pectoris, congestive heart failure and ischemic damage due to coronary artery bypass surgery. Because of its high specificity and sensitivity in the myocardial tissue, cTnI has recently become the most preferred biomarker for myocardial infarction. The Troponin I test is a simple test that utilizes a combination of particle-conjugated anti-cTnI antibodies and a capture reagent to selectively detect cTnI in whole blood, serum or plasma.



Interpretation of the test results

Positive: two distinct red lines appear. One line forms in the Control Line region (C) and another line forms in the Test Line region (T).

Negative: one red line appears in the Control Line region (C). No apparent red line appears in the Test Line region (T).

Invalid: the Control Line is not being formed. In this case the result is invalid, even if the test result is visible. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

D-Dimer

D-Dimer is a rapid test for the qualitative detection of D-Dimer in whole blood or plasma with >99.9 % accuracy. The D-Dimer - cut-off-level is 500 ng/mL.

The test is intended as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep venous thrombosis (DVT) and pulmonary embolism through visual interpretation of colour development in the test device, which is a sandwich immunoassay.

Each kit contains: 10 D-Dimer test devices, 10 disposable pipettes, buffer solution (10 ampules), 1 package insert.

Material required but not provided: tubes for collection of blood samples, lancets (for whole blood) and a timer.

Test performance

- Collect whole blood from the fingertip.
- Allow the D-Dimer test device, specimen, and/or controls to equilibrate to room temperature (15-30°C/59-86 °F) prior to testing.
- Remove the test device from the sealed pouch and use it as soon as possible.

  Best results will be obtained if the assay is performed within one hour.
- Place the test device on a clean and level surface.

Plasma

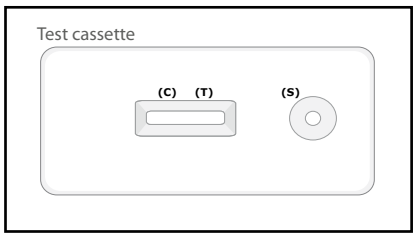
- Hold the provided pipette vertically and transfer 1 drop of plasma into the round specimen well (S) of the test device.
- Add 1 drop of the provided buffer solution.
- Start the timer.

Whole Blood

- Transfer 2 drops of whole blood (approximately 50 µl) into the round specimen well (S) of the test device.
- Add 1 drop of the provided buffer solution.
- Start the timer.
- Read the result after 10 minutes. Do not read results after more than 20 minutes.

Background

D-Dimer testing was originally developed in the diagnosis of disseminated intravascular coagulation (DIC). In the 1990s, it turned out to be useful in diagnosis of thromboembolic process. D-Dimer is a fibrin degradation product, a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. During coagulation of blood, fibrinogen is metabolized to fibrin by thrombin activation. Fibrin consists of D- and E- units. The cleavage of fibrin leads to so called D-Dimers. D-Dimer concentration may be determined by a blood test to help diagnose thrombosis. Since its introduction in the 1990s, it has become an important test performed in patients with suspected thrombotic disorders. While a negative result practically excludes thrombosis, a positive result can indicate thrombosis but does not rule out other potential etiologies. Its main benefit therefore is to exclude thromboembolic disease where the probability is low.
D-Dimer testing is of clinical use when there is a suspicion of deep venous thrombosis (DVT) or pulmonary embolism (PE). In patients suspected of disseminated intravascular coagulation (DIC), D-Dimer testing may support the diagnosis.



Interpretation of the test results

Positive: two distinct red lines appear. One line forms in the Control Line region (C) and another line forms in the Test Line region (T). There is an increased concentration of D-Dimer found in the specimen.

Negative: one red line appears in the Control Line region (C). No apparent red line appears in the Test Line region (T).

Invalid: the control line is not being formed. In this case the result is invalid, even if the test result is visible. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

Strep A

Strep A is a rapid test for the qualitative detection of streptococci antigen group A in throat swabs with 97.3 % accuracy. The Strep A cut-off level is $5x10^4$ CFU/mL.

The test is able to detect group A streptococci in nasal swabs by color change of a color line (result line) which forms on the test strip.

Each kit contains: 20 Strep A test devices, 20 pipettes, 20 swabs, 20 extraction tubes, reagent bottles, a workstations and 1 package insert.

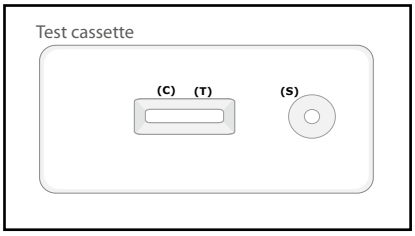
Material required but not provided: timer.

Test performance

- Dab the back of the throat and tonsils with the sterile swab.
- Set the extraction tube into the workstation and fill 4 drops of Reagent A into it.
- Fill in 4 drops of reagent B. Mix the solution by rotating the tube gently.
- Insert the swab immediately with the sample collected in the tube.
- Allow it stands at room temperature for 1-15 minutes. Then squeeze out as much liquid as possible from the swab. Discard the swab. The mixture is now ready for testing.
- Remove the test device from the seal.
- Use the supplied dropper and apply 3 drops (about 75 microliters) of the extracted solution from the vial to the sample well (S) of the test device.
- Start the timer.
- Read the result after 10 minutes. Do not read results after more than 20 minutes.

Background

Beta-hemolytic group A streptococci are the main reason for infections of the upper respiratory tract. Tonsilitis, Pharyngitis und Scarlet Fever are typical diseases. It has been shown that an early diagnosis and treatment of streptococci related Pharyngitis will reduce the severity of symptoms and decrease the amount of further complications like rheumatic fever or Glumerulonephritis. A conventional detection method by isolation of the streptococcus bacteria takes 4-48 hours, which is too long for a fast treatment. The Strep A rapid test facilitates a direct and efficient chair side diagnosis.



Interpretation of the test results

Positive: two pink colored lines appear on the membrane. One line should be in the control region (C) and another line in the test region (T). The test has proven the presence of group A streptococci.

Negative: only one pink colored line appears in the control region (C). No visible line appears in the test region (T). There were no group A streptococci detected.

Invalid: if the control line fails to appear in the control region (C), the test result is invalid. The absence of the control line may indicate an error in the test procedure or that the ingredients of the assay are not functional.

Influenza A/B

Influenza A/B is a rapid test for the qualitative detection of Influenza type A and B antigens from nasal swab specimens with 97% accuracy. The cut-off level for Influenza A and B is $1 \cdot 10^4$ CFU/mL.

The test is able to detect Influenza type A and B antigens (nucleoprotein) extracted from nasal swab specimens. The test is able to detect various Influenza A subtypes including H1N1 and H3N2.

Each kit contains: 10 Influenza A/B test devices, 10 disposable pipettes, 10 sterile swabs, 10 extraction tubes, 1 buffer solution and 1 package insert.

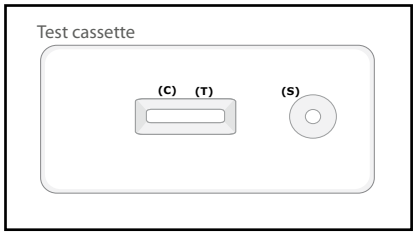
Material required but not provided: timer.

Test performance

- Gently collect nasal specimen with the swab.
- Place the test device on a clean and level surface.
- Hold the extraction buffer bottle vertically and add 20 to 24 drops of the extraction buffer solution to the extraction tube.
- Immediately insert the swab with collected nasal swab specimen, compress the bottom of the tube and rotate the swab vigorously to mix the reagents for at least 1 minute.
- Press the swab against the inside of the tube and expunge as much liquid as possible from the swab. Discard the swab. Mix the contents of the tube by gentle swirling.
- Fill the provided pipette with the mixture.
- Hold the pipette above the sample well of the test device and squeeze 3 drops into the well.
- When the mixture is absorbed, take the buffer bottle and put 2 drops of pure buffer solution onto the sample well.
- Start the timer.

Background

Influenza, commonly known as flu, is an infectious disease of birds and mammals caused by RNA viruses of the family Orthomyxoviridae (the influenza viruses). In humans, common symptoms of influenza are fever, sore throat, muscle pains, severe headache, coughing, weakness and general discomfort. In more serious cases, influenza causes pneumonia, which can be fatal, particularly in young children and elderly patients. Although influenza sometimes is mistaken for the common cold, influenza is a much more severe disease and is caused by a different type of virus. Typically, influenza is transmitted from infected mammals through the air by coughs or sneezes, creating aerosols containing the virus, and from infected birds through their droppings. Influenza can also be transmitted by saliva, nasal secretions, feces and blood.



Interpretation of the test results

Positive: two or three distinct red lines appear. One line should be in the control line region (C) and another line should be in the test line region (A or/and B).

Negative: in the control region (C) a red line appears. No apparent red or pink line appears in the test line regions (A and B).

Invalid: the control line is not being formed. In this case the result is invalid, even if a test result is visible. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

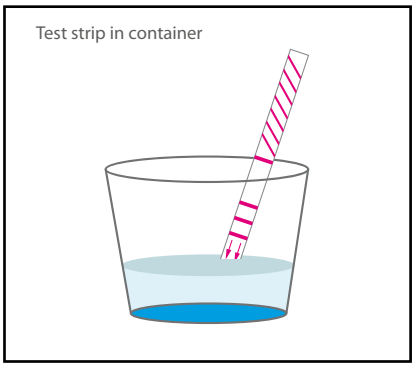
Microalbumin

Microalbumin is a rapid test for the qualitative detection of microalbumin from 20 µg/ml in urine with 97.5 % accuracy.

Microalbumin test is able to detect microalbumin through visual interpretation of a certain colour development on the test strip.

Each kit contains: 25 Microalbumin dipsticks (test strips in tube), 1 package insert.

Material additionally needed: sample collecting containers, a a timer and a centrifuge.



Test performance

- Urine sample to be collected in a clean and dry container.
- Take the test strip out of the tube and immediately close the tube again.
- Hold the test strip at the handle (part with transverse streaks). Place or hold it upright in the sample container.
- Leave it in the sample until a redish liquid front reaches the test line (T) of the test strip. This will take about 10 to 15 seconds.
- As soon as the sample has reached the (T) region, take the test strip out of the container and place it on a clean and plain surface that does not withdraw liquid.
- Start the timer.
- Read the result after 5 minutes. Do not read results after more than 10 minutes.

Background

The permanent excretion of small amounts of albumin (20 to 200 ug/ml) in urine is called microalbuminuria. In type 1 diabetic patients, microalbuminuria may be the first sign of kidney damage and point to an incipient diabetic nephropathy. Without appropriate therapeutic intervention, the amount of excreted albumin increases, thus being called macroalbuminuria. Renal failure is likely to follow. In type 2 diabetic patients, the early diagnosis and treatment of diabetic nephropathy is particularly important, because in addition to renal dysfunction there are some cardiovascular risks, too. Under physiological conditions, albumin is being filtrated glomerular in small amounts and reabsorbed tubularly. Additionally to renal dysfunction/albuminurie, an increase in albumin may be caused by physical activity, urinary tract infection, hypertension, heart failure, or surgical interventions. In these cases a transient albuminuria is diagnosed and the increased albumin excretion disappears after eliminating these factors.

Interpretation of the test results

Positive: only one pink coloured line appears in the control region (C). No visible line appears in the test region (T). There was microalbumin detected in the sample.

Negative: two pink coloured lines appear on the membrane. One line should be in the control region (C) and another line in the test region (T). The test doesn't show any presence of microalbumin.

Invalid: if the control line fails to appear in the control region (C), the test result is invalid. The absence of the control line may indicate an error in the test procedure or that the ingredients of the assay are not functional.

NOTES

Performance characteristics of NanoRepro AG rapid tests

Product	Sensitivity	Specificity	Accuracy	Cut-off Level	Temperature
Home-Tests					
FAMILY PLANNING LINE					
FertiQUICK	97.0 %	94.7 %	95.1 %	20 Mio/mL	2-30°C
OvuQUICK	>99.9 %	>99.9 %	>99.9 %	25 mIU/mL	4-30°C
VagiQUICK	86.0 %	94.0 %	90.0 %	$6.0 \cdot 10^3$ CFU/mL	2-30°C
GraviQUICK	>99.9 %	>99.9 %	>99.9 %	25 mIU/mL	4-30°C
GraviQUICK Early GraviQUICK Frühtest***	>99.9 %	>99.9 %	>99.9 %	10 mIU/mL	4-30°C
MenoQUICK	>99.9 %	>99.9 %	>99.9 %	25 mIU/mL	4-30°C
PREVENTIVE HEALTHCARE LINE					
GlutenCHECK	98.0 %	96.7 %	98.0 %	5 U/mL	10-27°C
Heli-C-CHECK	94.0 %	97.7 %	96.9 %	20 U/mL	10-27°C
FerritinCHECK EisenCHECK***	97.6 %	96.9 %	95.2 %	20 ng/mL	10-27°C
FOBCHECK	97.1 %	98.0 %	98.6 %	40 ng/mL	4-30°C
TSH CHECK	96.4 %	95.2 %	95.7 %	5 µIU/mL	2-30°C
Alkohol TEST	96%; 98.6%; >99.9 %	tbd	98.0 %	0.2‰; 0.5‰; 0.8‰	4-30°C
DrugTEST	>98.5 %	>99 %	>98.5 %	see PI sheet	4-30°C
ALLERGY LINE					
AllergoCHECK	93.7 %	98.3 %	96.6 %	0.35 U/mL	2-30°C
MilkCHECK MilchCHECK***	92.3 %	>99.9 %	97.1 %	0.7 U/mL	4-25°C
For professional use only					
Infectious Diseases					
Strep A	99.9 %	87.0 %	97.0 %	$5x10^4$ CFU/mL	2-30°C
Influenza A/B	99.0 %	96.0 %	95.8 %	strain A+B $1*10^4$ CFU/mL	2-30°C
Molecular Markers					
Troponin I	97.9 %	98.9 %	98.5 %	1 µg/mL	2-30°C
D-Dimer	96.0 %	92.3 %*	95.0%**	500 ng/mL	2-30°C
Microalbumin	96.0 %	98.6 %	97.5 %	20 µg/mL	2-30°C

*The analytical specificity/Die analytische Spezifität

** The analytical accuracy was determined with a gold standard./
Ermittelt wurde die analytische Genauigkeit mit einem Goldstandard.

*** German/Deutsch

IMPRINT

Revision 2018-06

Editor:
NanoRepro AG
Untergasse 8
35037 Marburg

Tel.: +49 (0) 6421 95 14 49
Fax: +49 (0) 6421 95 14 51
info@nanorepro.com
www.nano.ag

Fotos:
iStock, Fotolia