ALWEX GmbH

Alwex rapid tests | 2018

About us

Senova Gesellschaft für Biowissenschaft und Technik is a medium-sized and owner-managed company based in Weimar, which specializes in high-quality immunological rapid tests. The company currently employs more than 30 people in research and development, production, administration, sales, logistics, purchasing, IT and quality assurance. Senova point-of-care tests are based on the well-established lateral flow technology or on the innovative 3D immunofiltration. In addition to the detection of numerous biomarkers for home use as well as professional use in the human and veterinary field, the product range also includes rapid tests for bioterror prevention. Since 2011, the company has been certified according to ISO 13485 and 9001 as a medical device manufacturer for in vitro diagnostics (IVD).

Research & development

Senova develops new rapid test systems for the detection of biomarkers, viruses and microorganisms or establishes and optimizes tests on existing platforms. The team is equipped with state-of-the-art laboratories and tools for varying demanding solutions. In addition to the point-of-care IVD development, all components such as customer-specific conjugates and lyophilisates are offered for the successful test set-up. The portfolio is rounded off by validation services such as the IVD performance assessment, storage and transport stability tests, feasibility studies as well as quality assurance.

Production

Due to the fully automated master sheet production the output has been optimized to 20,000 test strips per hour. At the same time, batch sizes of up to 5,000 vials can be achieved with Midscale GMP lyophilisation. The test cassettes and dipsticks are manufactured under cleanroom conditions with controlled humidity. Modern methods such as laser marking and ultrasonic welding, as well as the cooperation with preferred regional suppliers, characterize the flexible and extraordinarily reliable production process. From our 650m^2 pallet warehouse products are shipped to our international clientele. The paperless management of all processes ensures the consistently high quality standard.

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Coming soon

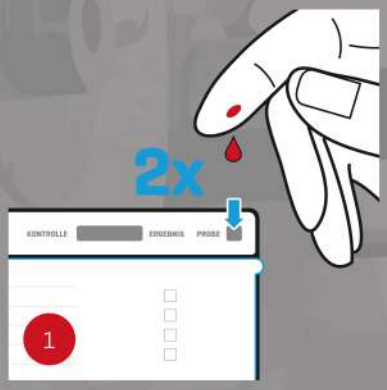
Senova is always improving it's portfolio of analyts. The following assays are currently in development.

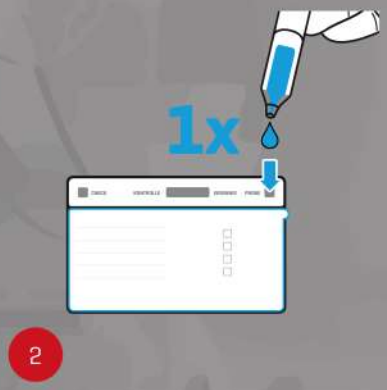
- TSH
- PSA
- CRP
- HbA1C
- Vitamins
- Cystantin C
- Chlamydia
- Gonorrhea
- Hepatitis C
- HIV

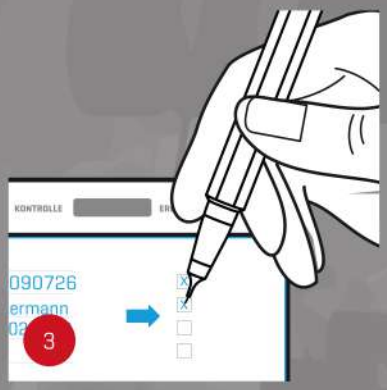
For any further details about our existing portfolio, feel free to contact us.

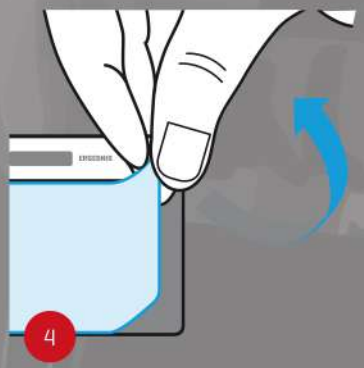
DEDIACARD Cardio

This combi-test is used for the qualitative detection of two different biomarkers as a perfect junction in the heart infarction diagnosis. The highly specific myocardial infarction biomarker Troponin I can be detected in the blood earliest 8 hours after an ischemic event, due to its delayed release.
Even a 12-lead ECG presents without abnormalities in 25% of infarction patients. Therefore in some cases a definite diagnosis of acute infarction is not possible. This is why DEDIACARD Cardio combines Troponin I (TnI) with a second biomarker:
The heart-type fatty acid binding protein (hFABP) is the most effective marker for ruling out an acute myocardial infarction within the first 24 hours after the symptoms appear. This cytoplasmic protein is rapidly released into the blood by heart muscle cells after an ischemic event and can be detected in blood samples 20 minutes after symptom onset. The concentration remains high for around 21 hours and then returns to its natural level.









technical details

Cut-Off	Troponin 0,5 ng/ml; hFABP 7 ng/ml
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	human whole blood from venipuncture or finger prick, plasma, serum
Specificy	Troponin I 98%; hFABP 75,5%
Sensitivity	Troponin I 98%; hFABP 90 %

Content of the kit: single-use units each with one test cassette, buffer solution and disposable pipette, one manual per kit

Material required but not provided: tubes for collection of blood samples, lancets (only for whole blood from fingertip), centrifuge (for plasma/serum), a timer

Article code	Kit size
DCC-005	5 Tests
DCC-010	10 Tests

This qualitative immunological rapid test is designed as an aid for professional use in the detection of a myocardial infarction. Cardiac Troponin I (cTnI) is a protein that occurs in the heart muscle as a complex with Troponin T and Troponin C.
Together with Tropomyosin, it regulates the structural integrity of the calciumsensitive ATPase activity of Actomyosin in striated skeletal and muscle tissue. In the event of a myocardial damage, the complex is broken up. The individual elements are released into the blood and can be detected for many hours after the beginning of an infarction.Troponin I levels remain high for 8 days after the first release. This provides a large time frame for detecting a damage to the heart tissue. Due to its high specificity and sensitivity to myocardial tissue, Troponin I has become the biomarker of choice for myocardial infarctions.

technical details

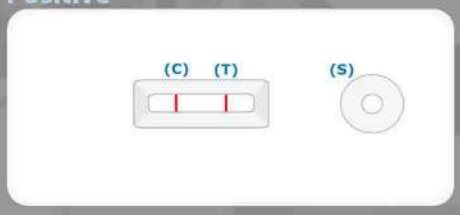
Cut-Off	0,5 ng/ml
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	human whole blood from venipuncture or finger prick, plasma, serum
Specificy	98%
Sensitivity	98%

Content of the kit: Troponin I test devices in pouch, disposable pipettes, buffer solution, one manual per kit

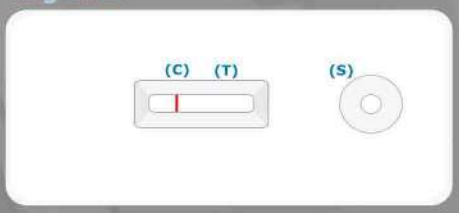
Material required but not provided: tubes for collection of blood samples, lancets (only for whole blood from fingertip), centrifuge (for plasma/serum), heparinised capillaries and dispensary bulb (for whole blood from fingertip), a timer

Article code	Kit size
TPI-005	5 Tests
TPI-010	10 Tests
TPI-020	20 Tests

Positive



Negative



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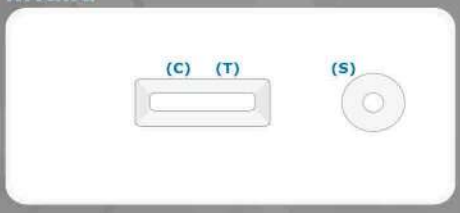

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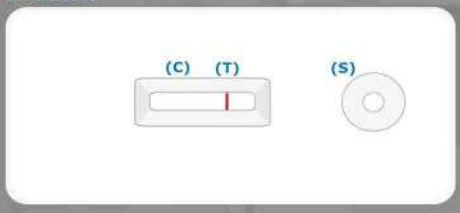


Interpretation of the test results

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 Troponin I 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.

D-Dimer

The qualitative immunological rapid 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. 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. 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.

technical details

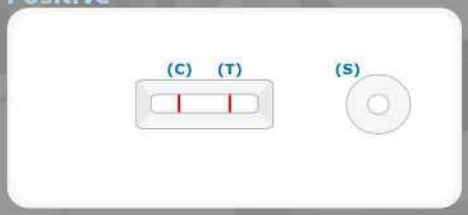
Cut-Off	500 ng/ml
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	human whole blood (anti-coagulated), plasma
Accuracy:	> 99%
Sensitivity	> 99%

Content of the kit: D-Dimer test devices in pouch, disposable pipettes, buffer solution, one manual per kit

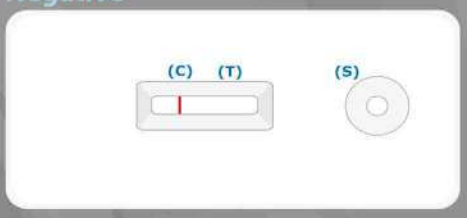
Material required but not provided: tubes for collection of blood samples (anti-coagulation with citrat or heparin required), lancets (for whole blood), and a timer

Article code	Kit size
DDM-005	5 Tests
DDM-010	10 Tests

Positive



Negative



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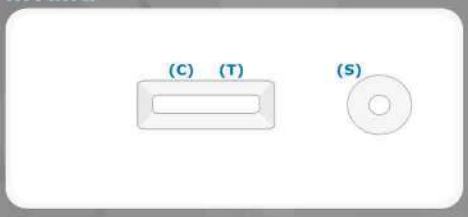

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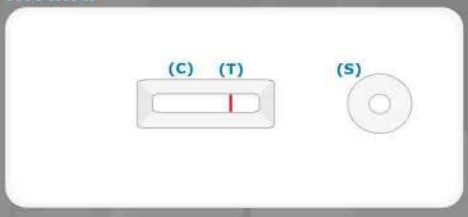


Interpretation of the test results

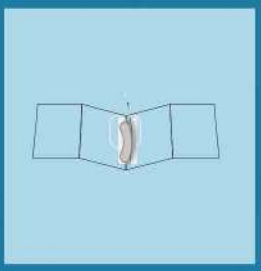
Positive
Two distinct red lines appear. One line forms in the Control Line region (C) and another line forms in the Test Line region (T). There is an increased concentration of D-Dimer found in the specimen.

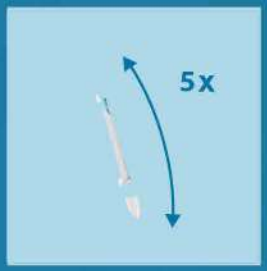
Negative
One red line appears in the Control Line region (C). No apparent red line appears in the Test Line region (T).

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.

FOB (fecal-occult blood)

This test is a rapid one-step test for the qualitative detection of human hemoglobin in fecal samples. FOB is designed to help diagnose gastrointestinal disorders. 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.





technical details

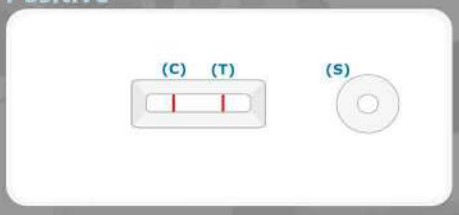
Cut-Off	10 ng/ml
Read-out time	5 minutes
Shelf life	18 months at +2-30°C
Sample matrix	feces
Sensitivity	> 95,3%
Specificity	> 99,1%

Content of the kit: FOB test devices in pouch, tubes for sample taking (filled with buffer solution), sample collectors, one manual per kit

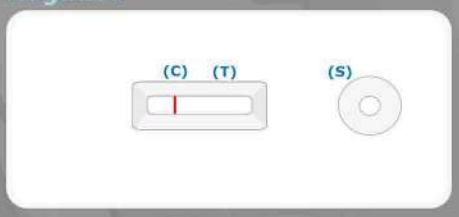
Material required but not provided: gloves and a timer

Article code	Kit size
FOB-010	10 Tests
FOB-020	20 Tests
FOB-050	50 Tests

Positive



Negative



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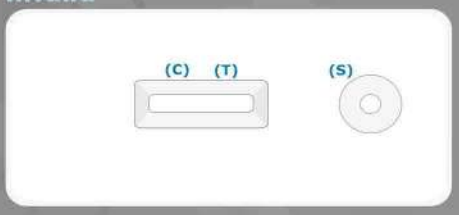

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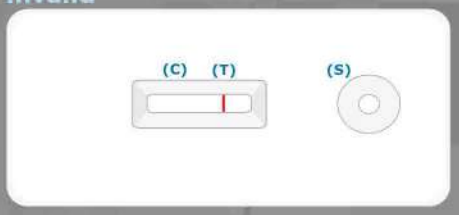


Interpretation of the test results

A red band opposite the (C) symbol indicates the test has worked correctly.

Negative

The test result is negative if a red line appears in the (C) marked field, and no line appears in the (T) field.

Positive

A red band opposite the (T) symbol (irrespective of the intensity) indicates positive result meaning the test has detected blood in fecal sample.

Invalid

Test result is invalid if the control line (C) is not visible in 5 minutes. The test failed or the test procedure was not followed properly.

Microalbumin

Microalbumin is a rapid test for the qualitative detection of microalbumin in urine. 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.

technical details

Cut-out	20 µg/ml
Read-out time	5 minutes
Shelf life	18 months at +2-30°C
Sample matrix	urine
Accuracy	97,5 %
Sensitivity	96 %
Specificy	98,6 %

Content of the kit: Microalbumin dipsticks (test strips in tube or single pouched) and one manual per kit

Material required but not provided: sample collecting containers, a timer, centrifuge

Article code	Kit size
MAB-025	25 Dipsticks in tube
MAB-020	20 Dipsticks single pouched

Test stripe in container

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 in order.

Influenza A/B

Influenza A/B is a rapid test for qualitative detection of Influenza A, including subtypes like H1N1 and H3N2, as well as Influenza B antigen. 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 with 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.

technical details

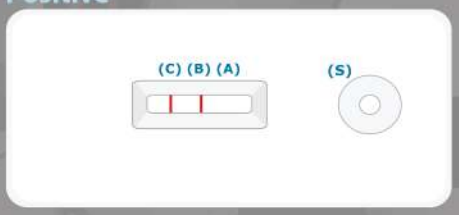
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	nasal swab
Specificy	95%
Sensitivity	99%
Accuracy	>97%

Content of the kit: Influenza A/B test devices, disposable pipettes, sterile swabs, extraction tubes, buffer solution, workstation and one manual per kit

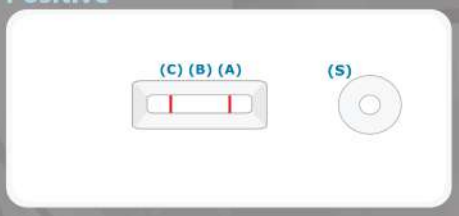
Material required but not provided: a timer

Article code	Kit size
IFA-010	10 Tests

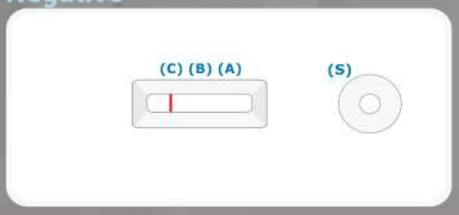
Positive



Positive



Negative



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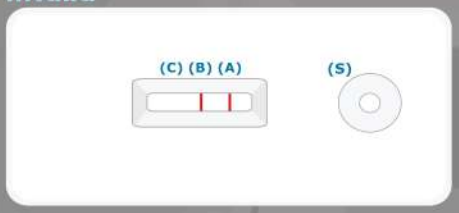

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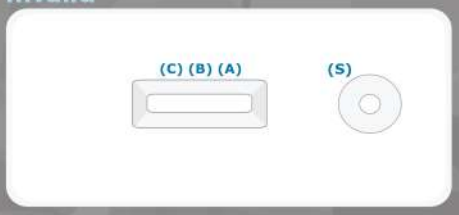


Interpretation of the test results

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.

DEDIATEST Ebola

DEDIATEST ebola is a rapid visually read chromatographic immunoassay for the qualitative detection of Ebola virus antigen. Ebola hemorrhagic fever (Ebola HF) is a severe, often fatal disease of humans and nonhuman primates (monkeys, gorillas and chimpanzees) that has appeared sporadically. The virus is one of two members of a family of RNA viruses called the Filoviridae. There are five identified subtypes of Ebola virus. 90% of the outbreaks are caused by Ebola Zaire strain.

technical details

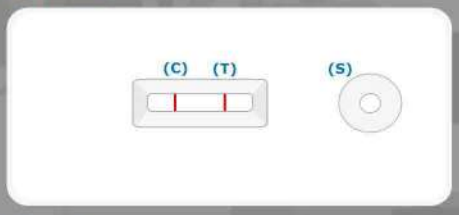
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	human serum and throat swab
Analytic Sensitivity	≤ CT23
Specificy	98 %

Content of the kit: Ebola test devices, disposable pipettes, swabs (sterile), extraction tubes, reagent bottle, workstation, one manual per kit

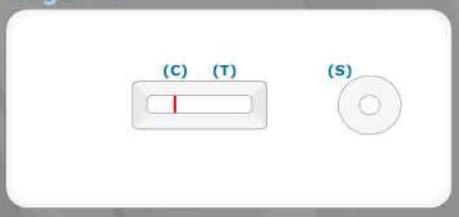
Material required but not provided: a timer, sample collection device (for serum)

Article code	Kit size
DTE-020	20 Tests

Positive



Negative



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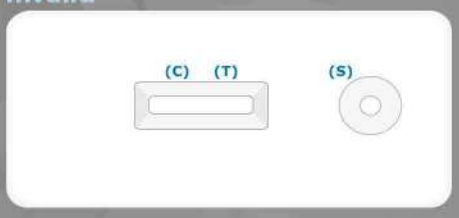

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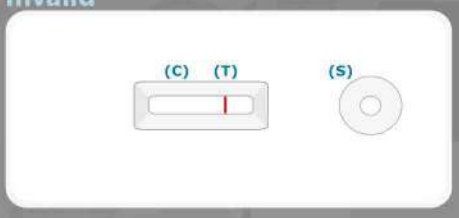


Interpretation of the test results

A red band opposite the (C) symbol indicates the test has worked correctly.

Negative

The test result is negative if a red line appears in the (C) marked field, and no line appears in the (T) field.

Positive

A red band opposite the (T) symbol (irrespective of the intensity) indicates positive result meaning the test has detected Ebola virus antigens in sample.

Invalid

The test result is invalid if the control line (C) is not visible in 10 minutes. The test failed or the test procedure was not followed properly.

Strep A

Strep A is a rapid test for the qualitative detection of streptococci antigen group A in throat swabs. 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.

technical details

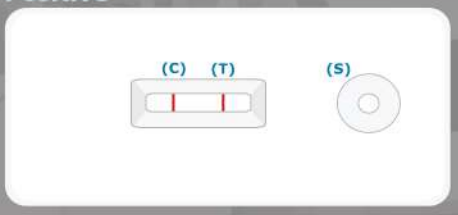
Read-out time	5 minutes
Shelf life	18 months at +2-30°C
Sample matrix	throat swab
Accuracy	99 %
Sensitivity	> 99 %
Specificy	> 99 %

Content of the kit: Strep A test devices/dipsticks, disposable pipettes (only for cassette test), swabs (sterile), extraction tubes, reagent bottle set, workstation, one manual per kit

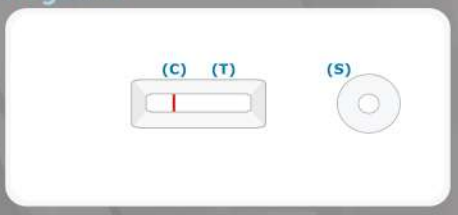
Material required but not provided: a timer

Article code	Kit size
SAD-020	20 Tests (Dipsticks)
SAC-020	20 Tests (Cassette test)

Positive



Negative



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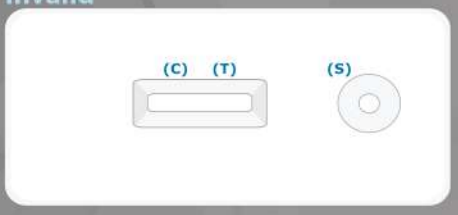

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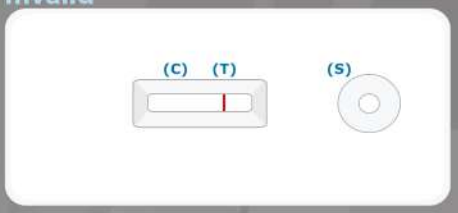


Interpretation of the test results

A red band opposite the (C) symbol indicates the test has worked correctly.

Negative

The test result is negative if a red line appears in the (C) marked field, and no line appears in the (T) field.

Positive

A red band opposite the (T) symbol (irrespective of the intensity) indicates positive result meaning the test has detected Streptococcus A in throat swab sample.

Invalid

The test result is invalid if the control line (C) is not visible in 5 minutes. The test failed or the test procedure was not followed properly.

Histo H.p.

Histo H.p. (Helicobacter pylori) is a rapid test for the qualitative detection of the bacterium Helicobacter pylori in human tissue samples, taken from the preepyloric antrum during gastroscopy. This bacterium is the most common cause of painful inflammation of the stomach lining with nausea and abdominal discomfort.
The transfer of Helicobacter pylori usually takes place orally from person to person. Helicobacter pylori often behaves inconspicuously for many years before its permanent presence in the gastric mucosa irritates the epithelial cells, which leads to gastritis, a chronical inflammation in the stomach which may have further consequences. Helicobacter pylori bacterium can contribute to the development of diseases such as ulcers in the stomach and lymphoma progress (a type of cancer).

technical details

Read-out time	30 minutes
Shelf life	18 months at +2-30°C
Sample matrix	tissue taken from preepyloric antrum
Sensitivity	99%

Content of the kit: Histo HP reaction vessels containing lyophilised pellets, buffer solution (distilled water, 20 ml), disposable pipettes, one manual per kit

Material required but not provided: sample collecting equipment, a timer

Article code	Kit size
HHP-020	20 Tests

Interpretation of the test results

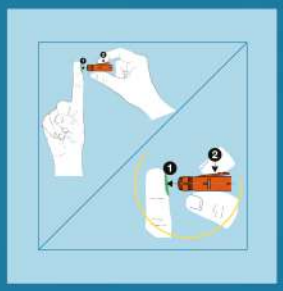
Positive
If Helicobacter pylori is present in the sample, a color change from yellow to red-violet / pink is visible. In the presence of only a small amount of Helicobacter pylori present, there may be a delay in color changing. Therefore, a negative test result must be checked again after 3 and after 24 hours.

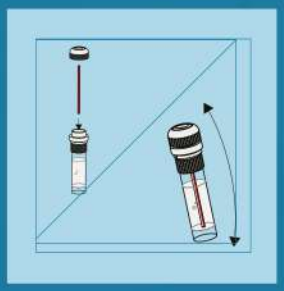
Negative
A negative test result is obtained if there is no color change within 24 hours. The solution remains yellow. A possible color change after more than 24 hours can also be interpreted as a negative test result.

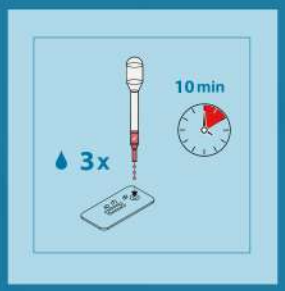
Invalid
If the dissolved lyophilisate does not turn yellow before introduction of the biopsate, but remains red-violet for a prolonged period, the test should not be used.

Helicobacter pylori

Helicobacter pylori is a rapid screening test for the qualitative detection of Helicobacter pylori antibodies in human whole blood. Helicobacter pylori is a small, spiral-shaped bacterium that lives on the surface of the stomach.
It is responsible for the etiology of a whole series of gastrointestinal disorders, including duodenal ulcers, gastric ulcers, non-ulcerous dyspepsia, and active and chronic gastric mucosa infections. Once infected, the human body develops antibodies against the bacterium as an immune response. Those antibodies can be detected in human blood even if the patient doesn't experience symptomes yet. A positive test result should b e confirmed by the physician with the help of a second diagnostic aid like a gastroscopy. Helicobacter pylori infections may be successfully treated with an antibiotic therapy.







technical details

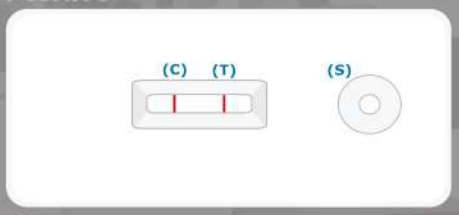
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	capillary whole blood
Sensitivity	94,03%
Specificy	97,73%
Accuracy	96,92%

Content of the kit: test cassettes, buffer solution bottles with sample dilution buffer, automatic sterile lancets for comfortable blood sampling, glass capillaries in plastic tubes, disposable pipettes, alcohol pads, plasters and manual

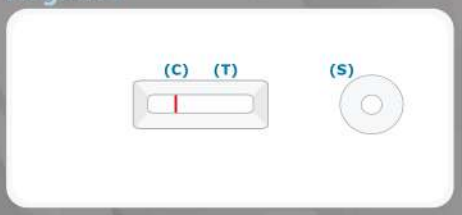
Material required but not provided: a timer

Article code	Kit size
HBP-010	10 Tests

Positive



Negative



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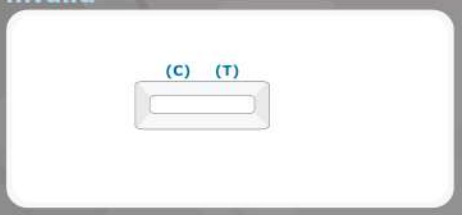

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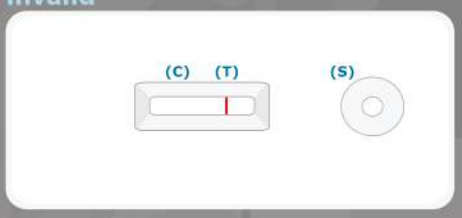


Interpretation of the test results

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.

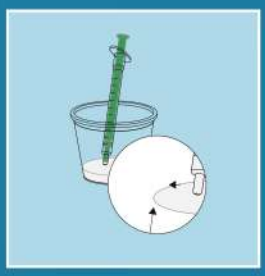
Negative

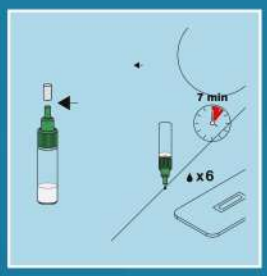
If only a Control line (C) is visible with no Test line (T), the test result is negative: Helicobacter pylori specific IgG antibody is not present in the blood sample.

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.

This rapid test determines whether the sperm count is in the normal range (according to the WHO) or not.
Unintentionally childless couples often ask themselves about the cause. If this is the case, an under-average sperm count in the seminal fluid may be one of the possible reasons for a successful fertilization.





technical details

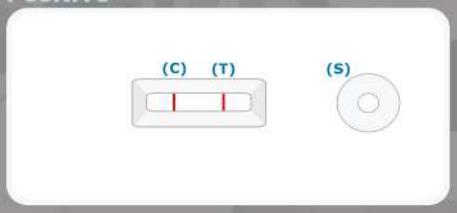
Read-out time	7 minutes
Shelf life	18 months at +2-30°C
Sample matrix	seminal fluid
Accuracy	95,10 %
Sensitivity	> 97 %
Specificy	94,68 %

Content of the kit: test cassettes, containers for sample collection, dropper bottles with buffer solution, syringes, a manual

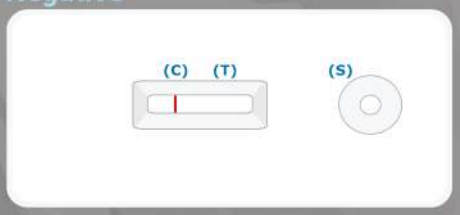
Material required but not provided: a timer

Article code	Kit size
MFY-010	10 Tests

Positive



Negative



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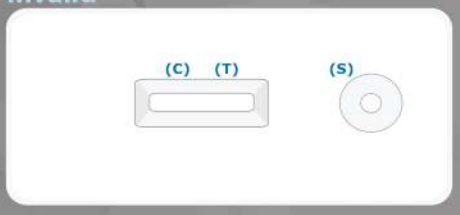

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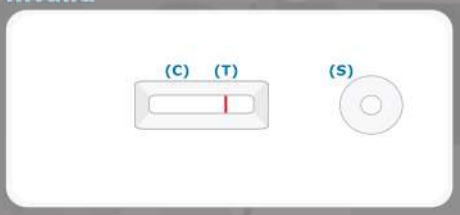


Interpretation of the test results

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

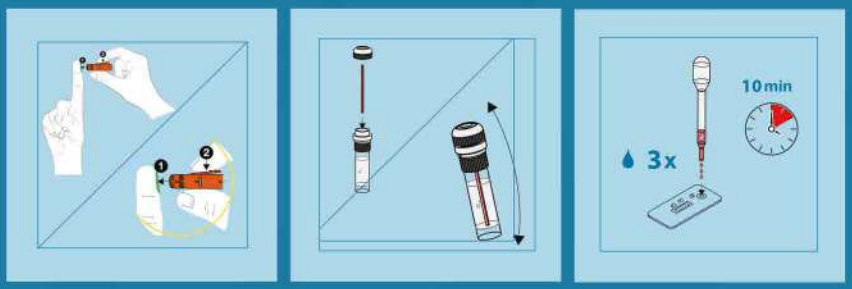
If there is only Control line (C) and NO Test line (T), the test result is negative. The sperm count is less than 20 million per milliliter. However, a negative test result alone does not prove the infertility.

Invalid

If there is no Control line (C) in the result window, the test did not run correctly and the results are not valid.

Iron deficiency

This rapid test is meant for the diagnosis of iron deficiency which can be caused by insuficient dietary intake and absorption of iron, or iron loss from bleeding (for example, menstrual bleeding, abnormal bleeding or ulcers). Iron deficiency prevalence is highest among young children and women of childbearing age. Thus, it has been shown during pregnancy or growth phase, and is known to cause serious health consequences. It is important that current body iron stores are sufficient. Iron is stored in protein complex as 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.



technical details

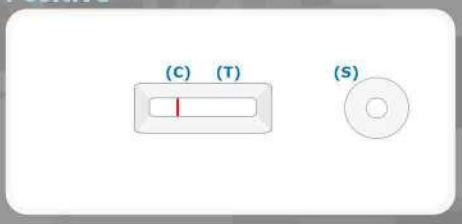
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	capillary whole blood
Specificy	96,92%
Sensitivity	97,56%
Accuracy	95,24%

Content of the kit: test cassettes, buffer solution bottles with sample dilution buffer, automatic sterile lancets for comfortable blood sampling, glass capillaries in plastic tubes, disposable pipettes, alcohol pads, plasters and manual

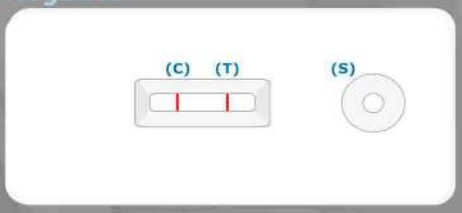
Material required but not provided: a timer

Article code	Kit size
IRD-010	10 Tests

Positive



Negative



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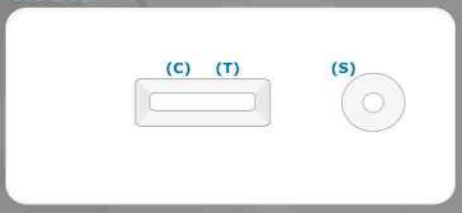

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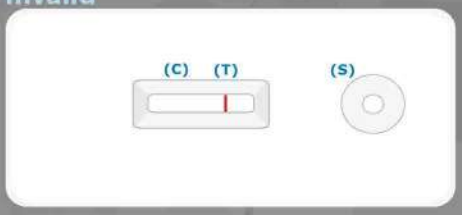


Interpretation of the test results

To read the test results simply determine whether a line is present or absent at the control (C) position.

Positive:

If 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 there are lines both at the Control (C) position and the Test (T) position, the test 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.

Drugs of abuse

This immunological rapid test for the qualitative detection of Amphetamine, Benzodiazepine, Cocaine, THC, Methadon and Morphine is designed to provide an immediately available, reliable screening result for the mentioned drugs of abuse as well as their metabolites. Usually drugs of abuse are highly effective psychotropic substances. The consumption of drugs involves a variety of dangers and long-term health and psychosocial problems are to be expected.

Test	Abb.	Calibrator	Cut-off (ng/ml)	Detection time in urine since last consumption
Amphetamin	AMP	D-Amphitamin	1.000	1-3 days
Benzodiazepin	BZO	Oxazepam	300	reg.c. up to 6 weeks occ.c. up to 3 days
Kokain	COC	Benzoylecgonin	300	up to 3 days
Marihuana	THC	11-nor-Δ9THC-9 COOH	50	reg. c. up tp 6 weeks occ. c. up to 4 days
Methadon	MTD	Methadon	300	2-3 days
Opiate	OPI	Morphin	300	up to 8 hours

technical details

Read-out time	5 minutes
Shelf life	18 months at +2-30°C
Sample matrix	urine
Accuracy	99%

Content of the kit: test cassettes and a manual

Material required but not provided: sample collection containers and a timer

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 off level which indicates drug abuse.

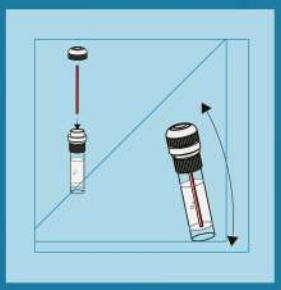
Negative:
If there are any lines at all at the Control (C) position and the Test (T) position, the test result is negative.

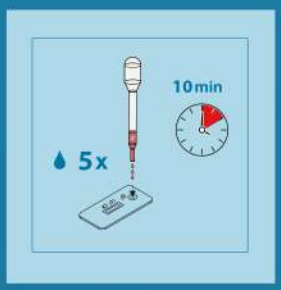
Invalid:
The result is invalid when no control line (C) or only a test line (T) is visible. Double-check if you have followed every step of the instruction correctly. Repeat the test using a new device and a new urine sample.

Article code	Kit size
DOB-010	10 Tests

Gluten intolerance

This rapid test is used to detect the presence of IgA tissue transglutaminase antibodies (tTG) in whole blood. It is suitable for both, an initial 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 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.





technical details

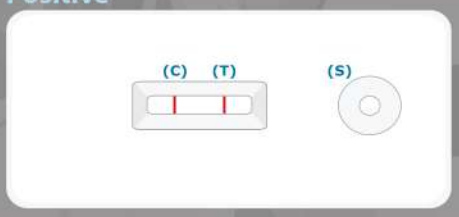
Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	capillary whole blood
Sensitivity	98%
Specificy	96,67%
Accuracy	98%

Content of the kit: test cassettes, buffer solution bottles with sample dilution buffer, automatic sterile lancets for comfortable blood sampling, glass capillaries in plastic tubes, disposable pipettes, alcohol pads, plasters and manual

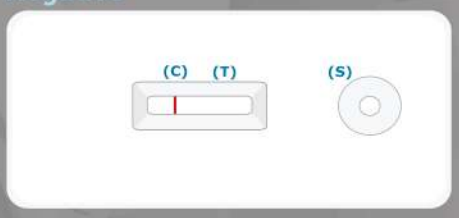
Material required but not provided: a timer

Article code	Kit size
GLI-010	10 Tests

Positive



Negative



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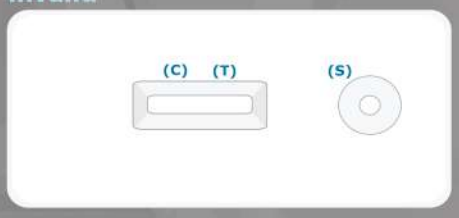

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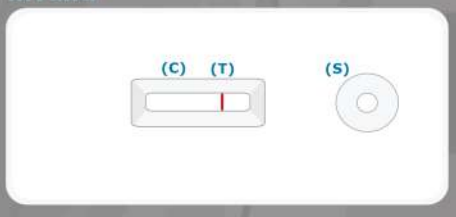


Interpretation of the test results

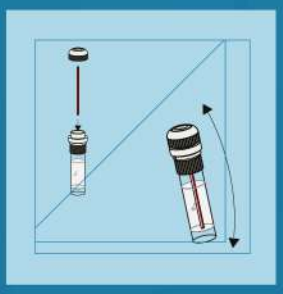
Positive
If a faint pink-to-red Control line (C) is visible in the result window along with a faint pink-to-read Test line (T), the test result is positive: blood sample contains gluten intolerance specific IgA antibodies - a high probability of existing gluten intolerance.

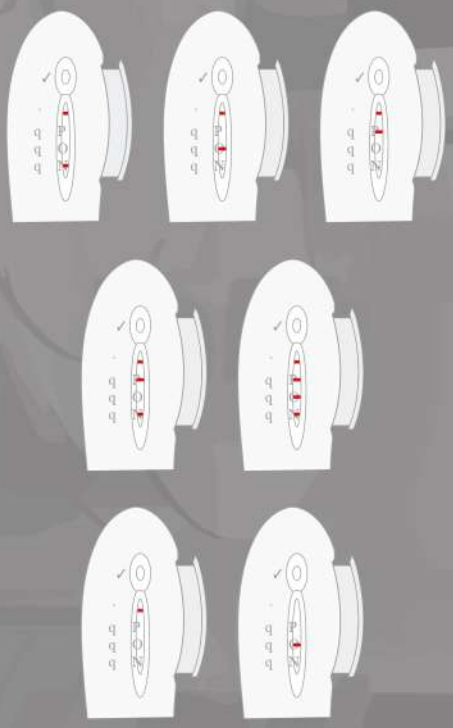
Negative
If only a faint pink-to-read Control line (C) is visible in the result window with no Test line (T), the test result is negative: gluten intolerance specific IgA antibodies are not present in the blood sample - no existing gluten intolerance.

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.

Allergy detection

This immunological rapid test for the qualitative detection of Immunoglobulin E (IgE) allergy antibodies to cat hair, grass pollen and house dust mite is performed with whole blood from finger prick. It is used to show an increased susceptibility to allergy: 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.





technical details

Read-out time	10 minutes
Shelf life	18 months at +2-30°C
Sample matrix	capillary whole blood
Accuracy	94%

Content of the kit: test cassettes, buffer solution bottles with sample dilution buffer, automatic sterile lancets for comfortable blood sampling, disposable pipettes, alcohol pads, plasters and manual

Material required but not provided: a timer

Article code	Kit size
ALD-010	10 Tests

Interpretation of the test results

A pink or red band opposite the C symbol indicates the test has worked correctly.

Positive

A pink or red band opposite the T1, T2 or T3 symbol (irrespective of the intensity) indicates that high levels of IgE allergy antibodies have been detected and you may have sensitivity to that particular allergen. T1: Allergy to cats T2: Allergy to dust mite T3: Allergy to grass pollen. A positive result is significant only when it is accompanied by 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.

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