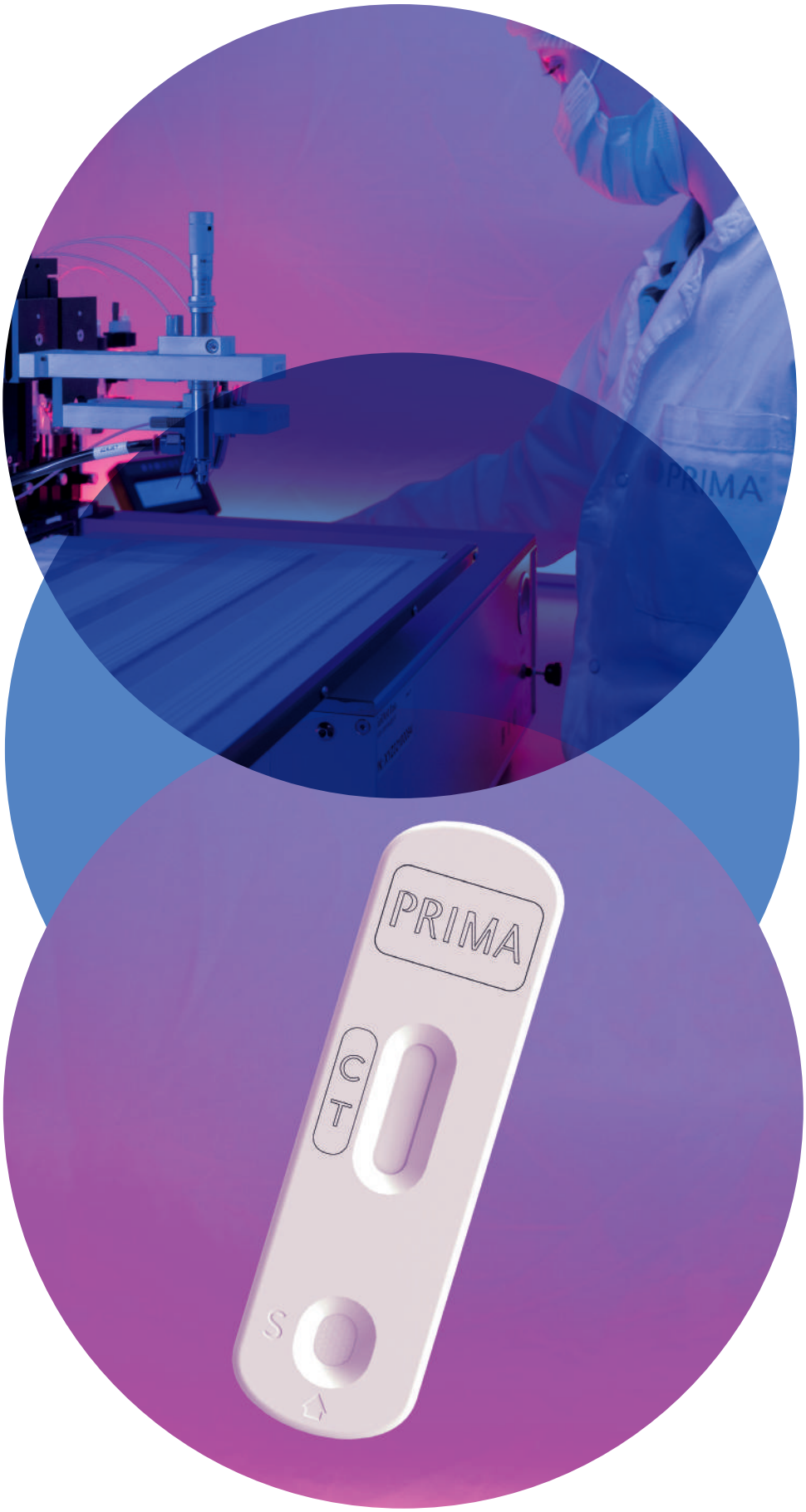


EASY TO USE | QUICK RESULTS | SWISS QUALITY

PRIMA

Stay healthy, live better

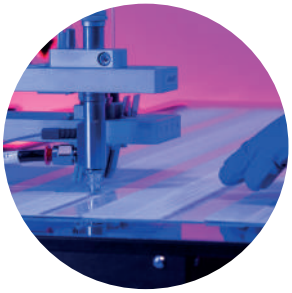
DIAGNOSTICS AT HAND

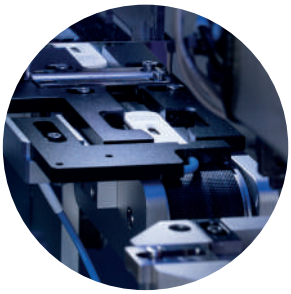
PRIMA® Lab SA has been **founded in Ticino, Switzerland, in 2014** from the founder's mission to build a company that **prevents disease** before a treatment is needed, by focusing on developing, manufacturing and selling **in-vitro medical devices**.

Our vision is to achieve an early detection of some **health conditions through rapid testing**, to enable lifestyle adjustment. We believe in a world where the **prevention** is a common and widespread practice, enabling early and fast actions to take care of oneself.

DYNAMIC, PROFESSIONAL AND QUALIFIED

We take care of our products at every stage.





Research & Development

Our in-house laboratory has strong expertise in qualitative and semi-quantitative lateral flow tests, with the ability in developing both single and multi-parameter devices. We perform the entire product development process, from the analysis of scientific validity, to the selection of raw materials, and the study of analytical and clinical performance. For selected partners we do work also as **Contract and Development Manufacturer Operator**.

Swiss manufacturing site

A fully **in-house automatic production** which includes different devices for different needs (cassette, strip, midstream and panty liner tests).

Quality Management System

Compliant with **ISO 13485:2016**, issued by Notified Boby MDC (Medical Device, Certification, Stuttgart, Germany).

Omnichannel sales

We support our partners with a multi-channel distribution, e.g. mass market, pharmacy chains, e-commerce, laboratories, private clinics, hospitals and vets with marketing and sales assistance. Our Regulatory Dept. offers **dedicated support** to notify and register devices in all the world.

Stay healthy, live better!

DIFFERENT BRANDS FOR DIFFERENT NEEDS

Our full portfolio consists in self, professional and veterinary testing,
with the following product lines.

PRIMA HOME TEST

Dedicated to human and pet self-testing.

REF	DESCRIPTION	N° OF TESTS	SAMPLE	SHELF LIFE	
CE2H88000KIT01EN	CELIAC DISEASE SCREENING TEST	1 TEST	CAPILLARY BLOOD	24 MONTHS	
800017-1	HELICOBACTER PYLORI TEST	1 TEST	CAPILLARY BLOOD	30 MONTHS	*
800016-1	HELICOBACTER PYLORI ANTIGEN TEST	1 TEST	FAECES	30 MONTHS	
800040-1	BOWEL FOB TEST	1 TEST	FAECES	30 MONTHS	
800062-1	HIV 1/2 SELF-TEST	1 TEST	CAPILLARY BLOOD	24 MONTHS	
800034-1	C-REACTIVE PROTEIN TEST	1 TEST	CAPILLARY BLOOD	36 MONTHS	
800060-1	STREP A TEST	1 TEST	THROAT SWAB	30 MONTHS	
100013-5	VAGINAL pH TEST	5 TESTS	VAGINAL SWAB	24 MONTHS	*
100058-3	URINARY TRACT INFECTIONS TEST	3 TESTS	URINE	24 MONTHS	*
800080-1	PROSTATE PSA TEST	1 TEST	CAPILLARY BLOOD	30 MONTHS	
820027-1	KIDNEYS ALBUMIN TEST	1 TEST	URINE	36 MONTHS	*
800025-1	IRON FER TEST	1 TEST	CAPILLARY BLOOD	30 MONTHS	
800018-1	ALLERGY IgE TEST	1 TEST	CAPILLARY BLOOD	36 MONTHS	*
100066-1	VITAMIN D TEST	1 TEST	CAPILLARY BLOOD	24 MONTHS	
19806-1	DRUG TEST	1 TEST	URINE	24 MONTHS	
820010-x	EARLY PREGNANCY TEST	1-2 TESTS	URINE	36 MONTHS	
820050-5	OVULATION LH TEST	5 TESTS	URINE	30 MONTHS	
820011-2	MENOPAUSE FSH TEST	2 TESTS	URINE	30 MONTHS	
100082-1	SPERM TEST	1 TEST	SPERM	24 MONTHS	*
100088-5	AMNIOCHECK	5 TESTS	AMNIOTIC FLUID	48 MONTHS	
PET100-1	GIARDIA PET TEST	1 TEST	PET FAECES	24 MONTHS	

* *The test is available until the end of the transition period related to the new Medical Devices Regulation. For further information, please contact the sales team.*

PRIMA PROFESSIONAL

Reserved for human professional use rapid tests.

REF	DESCRIPTION	N* OF TESTS	SAMPLE	SHELF LIFE
800060IP-20P	STREP A RAPID TEST	20 TESTS	THROAT SWAB	30 MONTHS
800034IP-20P	C-REACTIVE PROTEIN RAPID TEST	20 TESTS	WB / S	36 MONTHS
100066IP-20P	VITAMIN D RAPID TEST	20 TESTS	WB	24 MONTHS
800025IP-20P	IRON FER RAPID TEST	20 TESTS	WB / S	30 MONTHS
800040IP-20P	BOWEL FOB RAPID TEST	20 TESTS	FAECES	30 MONTHS
800077IP-20P	CELIAC RAPID TEST	20 TESTS	WB / S / P	24 MONTHS
800016IP-20P	HELICOBACTER PYLORI ANTIGEN RAPID TEST	20 TESTS	FAECES	30 MONTHS

PRIMA VETERINARY

Rapid tests dedicated to vets.

REF	DESCRIPTION	N* OF TESTS	SAMPLE	SHELF LIFE
800087-5	KI SCREENING TEST	5 TESTS	DOG'S URINE	18 MONTHS

The number of the tests in the box is customizable

GASTROINTESTINAL AREA
CELIAC DISEASE DETECTION

IVD CE 0483 IVDR CERTIFIED

NEW

CELIAC DISEASE SCREENING TEST

Rapid immunochromatographic manual self-test for the qualitative detection of anti-Deamidated Gliadin Peptide IgG and anti-tissue Transglutaminase IgA in human capillary blood sample for the screening of celiac disease

10 min. | 1 test

CELIAC DISEASE

Celiac Disease (CD), is a chronic inflammatory disorder of the small intestine, produced by the ingestion of dietary gluten products in genetically predisposed people. It is a multifactorial disease, including genetic and environmental factors. Environmental trigger is represented by gluten while the genetic predisposition has been identified in the major histocompatibility complex region which cause the presence of specific antibodies against gluten and its components. Celiac disease is not a rare disorder like previously thought, with a global prevalence around 1.5%. The reason of its under recognition is mainly referable to the fact that about half of affected people do not have the classic gastrointestinal symptoms, but they present non specific manifestations or have no symptoms at all.

GLIADIN AND CD ANTIBODIES

Gluten is a protein found in wheat, barley, rye, spelt and many other cereals, composed by glutenin and gliadin which is the part of gluten responsible of Celiac Disease. Recent studies have shown that celiac sufferers produce specific antibodies that are detectable in the blood. Among them, IgG anti-deamidated gliadin peptides (anti-DGP) and IgA anti-tissue transglutaminase (anti-tTG) antibodies show a high correlation with celiac disease, thus allowing high accuracy in screening for the disease.

WHO ARE THE INTENDED USERS

Symptomatic patients (e.g. diarrhoea, abdominal pain and bloating, weight loss, tiredness and/or headache), those with a family predisposition (risk of up to 20% for first-degree relatives), individuals with vitamin deficiencies (e.g. iron, ferritin, folic acid, vitamin D, vitamin B12 and calcium) and high risk groups (subjects with iron deficiency anaemia, Down syndrome, type 1 diabetes mellitus, osteoporosis).

WHY - BENEFITS

A self-test represents an important tool that is simple, rapid, and non-invasive in the screening process for potential celiac patients. It allows for the quick large-scale identification of individuals at risk, helping to prevent complications associated with the disease and to select those who require further diagnostic investigations.

TEST PRINCIPLE

CELIAC DISEASE SCREENING TEST is a manual immunochromatographic self-test device designed to detect the presence of IgG anti-DGP and IgA anti-tTG antibodies in capillary blood. When present, the target antibodies bind to gold nanoparticle-conjugated reagents, migrate via capillary action along the membrane, and produce visible colored lines at the specific test regions. In the absence of these antibodies, no test lines appear, indicating a negative result. A control line is always displayed to confirm correct test execution and reagent functionality.

TECH SPECS

	MEASURING RANGE	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
T1	min: 5 U/mL max: 302 U/mL	84.30%	90.10%	86.94%
T2	min: 12 U/mL max: 128 U/mL	98.31%	98.02%	98.17%

Performance data obtained by a clinical study on 266 real samples. Thermo Fisher Phadia 250 assay has been utilized as reference methods.

CLINICAL EVIDENCES

1. Lindfors, K., Ciacci, C., Kurppa, K. et al. Coeliac disease. Nat Rev Dis Primers 5, 3 (2019).

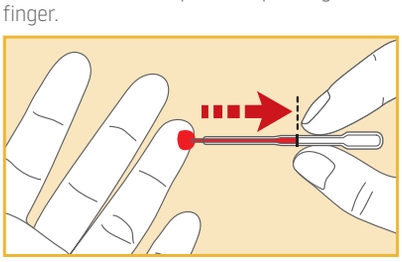
2. Al-Toma et al. European Society for the Study of Coeliac Disease (ESsCD) guideline for coeliac disease and other gluten-related disorders. United European Gastroenterol J. 2019 Jun;7(5):583-613.

3. King, et al. 2020. Incidence of Celiac Disease Is Increasing Over Time: A Systematic Review and Meta-Analysis. The American Journal of Gastroenterology 115 (4): 507–25.

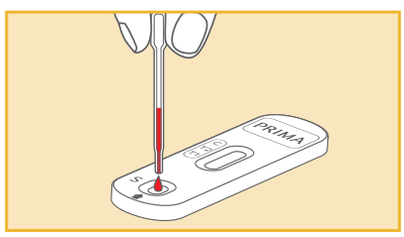
4. Parrinello G., Da Re M., Grizzo F., Camelliti S., Cozzi M., Marinoni F., Villalta D. Diagnostic accuracy of a novel point-of-care test for simultaneous detection of anti-transglutaminase IgA and anti-deamidated gliadin IgG antibodies. J Clin Lab Anal. 2024.

HOW TO USE IT

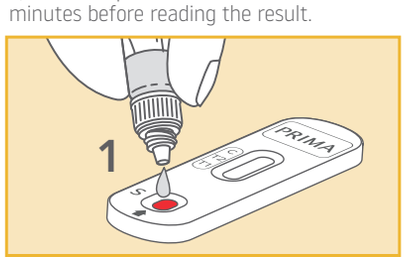
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 1 drop into the well and wait 10 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
CE2H88000KIT01EN	CELIAC DISEASE SCREENING TEST	1 TEST	24 MONTHS

IVD CE 0483

HELICOBACTER PYLORI TEST

Self-test for the determination of anti Helicobacter pylori antibodies in whole blood samples

HELICOBACTER PYLORI

Helicobacter pylori (Hp) is a bacterium that chronically infects more than half of the world's population and plays a causative role in the pathogenesis of chronic gastritis, peptic ulcer diseases, gastric cancer and mucosa associated lymphoid tissue lymphoma. The considerable burden of these Hp-related outcomes means that there is an acute demand for accurate diagnosis of this infection. Several detection methods have already been developed, such as culture, histological staining, the urea breath test (UBT) but a simple, non-invasive, inexpensive and accurate diagnostic test remains the goal. The simplest ways to detect infection is checking the presence of specific antibodies (IgG) produced by the immune system after encountering the bacterium and trying to eliminate it. HELICOBACTER PYLORI TEST can detect the presence of these antibodies in few minutes.

WHO ARE THE INTENDED USERS

Everyone who has gastric symptoms; the most common manifestations of these conditions are heartburn or pain in the upper part of the abdomen, especially when the stomach is empty. Other associated symptoms include nausea, feeling full, reflux, loss of appetite, weight loss and diarrhoea. Ulcers can sometimes bleed, causing anemia over long periods of time.

WHY - BENEFITS

In 1994, the National Institutes of Health recognized that most recurrent duodenal and gastric ulcers were caused by *H. pylori* and antibiotic treatment was recommended. In the same year, the International Agency for Research on Cancer (IARC) declared *H. pylori* to be a group I human carcinogen for gastric adenocarcinoma.

TEST PRINCIPLE

HELICOBACTER PYLORI TEST is an immunochromatographic test that detects the presence of anti-*Helicobater pylori* IgG antibodies in the blood, using special monoclonal antibodies conjugated with gold and integrated into the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
15 AU/mL	95,80%	84,20%	87,00%

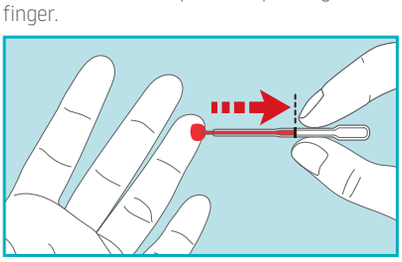
Performance data obtained by clinical study with 100 participants enrolled. IBL ELISA kit has been utilized as reference method.

CLINICAL EVIDENCES

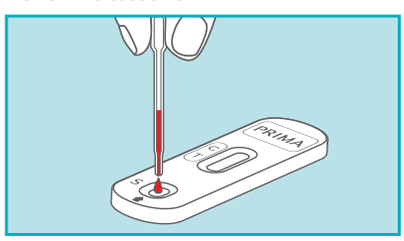
1. Mati Moyat, Dominique Velin. Immune responses to Helicobacter pylori infection. World J. Gastroenterol. 2014 may 21; 20(19): 5583-5593IgE." Journal of Allergy and Clinical Immunology. 2014;133(2):589-91.
2. Khean-Lee Goh, Wah-Kheong Chan, Seiji Shiota and Yoshio Yamaoka. Epidemiology of Helicobacter pylori Infection and Public Health Implications. Helicobacter, 2011 Sep;16(0 1):1-9.
3. Kyichi Adachi, Tomoko Mishiro, Shino Tanaka and Yoshikazu Kinoshita. Analysis of negative result in serum anti-pylori IgG antibody test in cases with gastric mucosal atrophy. J. Clin Biochem Nutr.2016 Sep;59(2):145-148.

HOW TO USE IT

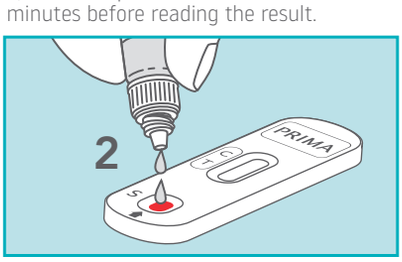
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800017-1	HELICOBACTER PYLORI TEST	1 TEST	30 MONTHS

IVD CE 0483

HELICOBACTER PYLORI ANTIGEN TEST

Self-test for detecting the presence of the Helicobacter pylori antigen in the faeces

HELICOBACTER PYLORI

Helicobacter pylori (Hp) is a bacterium that chronically infects more than half of the world's population and plays a causative role in the pathogenesis of chronic gastritis, peptic ulcer diseases, gastric cancer and mucosa associated lymphoid tissue lymphoma. The considerable burden of these *H. pylori*-related outcomes means that there is an acute demand for accurate diagnosis of this infection. Several detection methods have already been developed, such as culture, histological staining, the urea breath test (UBT) but a simple, non-invasive, inexpensive and accurate diagnostic test remains the goal. One of the simplest ways to detect infection is by checking the presence of specific antigens for the bacterium that are excreted through the faeces. HELICOBACTER PYLORI ANTIGEN TEST can detect the presence of these antigens in few minutes.

WHO ARE THE INTENDED USERS

Everyone who has gastric symptoms, ulcers can sometimes bleed, causing anemia over long periods of time.

WHY - BENEFITS

In 1994, the National Institutes of Health recognized that most recurrent duodenal and gastric ulcers were caused by *H. pylori* and antibiotic treatment was recommended. In the same year, the International Agency for Research on Cancer (IARC) declared *H. pylori* to be a group I human carcinogen for gastric adenocarcinoma.

TEST PRINCIPLE

HELICOBACTER PYLORI ANTIGEN TEST is an immunochromatographic test that detects the presence of specific *Helicobacter pylori* antigens in stools by using special monoclonal antibodies conjugated with gold and integrated into the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 ng/mL	95,20%	96,60%	96,00%

Performance data obtained by clinical study with 100 participants enrolled. ImmunoCard STAT!® HpSA® has been utilized as reference method.

CLINICAL EVIDENCES

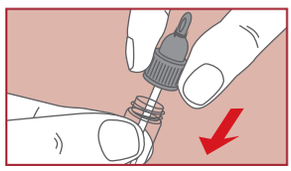
1. Shimoyama T. "Stool antigen tests for the management of Helicobacter pylori infection." World Journal of Gastroenterology. 2013;19(45):8188-91.
2. Ana Isabel Lopes, Filipa F Vale, Mónica Oleastro. "Helicobacter pylori infection - recent developments in diagnosis." World Journal of Gastroenterology. 2014 July 28; 20(28): 9299-9313.
3. Andreas Mentis, Philippe Lehours, and Francis Francis Megraud. "Epidemiology and Diagnosis of Helicobacter pylori infection". Helicobacter. 2015 Sep;20 Suppl 1:1-7.
4. Zagari RM, Rabitti S, Eusebi LH, Bazzoli F. "Treatment of Helicobacter pylori infection: A clinical practice update." Eur J Clin Invest. 2018 Jan;48(1). doi: 10.1111/eci.12857

HOW TO USE IT

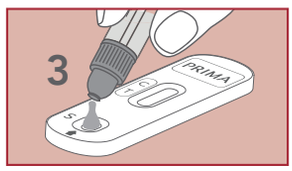
1) Attach the two adhesive surfaces of the stool-collecting sheet on the toilet seat surface.

2) Dip the stick into the faeces in three different points of the sample.

3) Screw on the cap, immersing the stick in the stool extraction liquid, and shake the vial.



4) Break the end of the cap, freeing the dropper portion. Dispense 3 drops of the diluted stool sample in the well shown on the cassette.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 vial with collection stick and dripper, containing the diluent; 1 small sheet for the collection of the sample; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800016-1	HELICOBACTER PYLORI ANTIGEN TEST	1 TEST	30 MONTHS

IVD CE 0483

BOWEL FOB TEST

Self-test for the detection of occult blood in the faeces

5 min. | 1 test

POSITIVE | NEGATIVE

FOB (FAECAL OCCULT BLOOD)

Faecal Occult Blood (FOB) is the presence in the faeces of blood that is not clearly visible to the naked eye. Occult blood may be the consequence of gastro-intestinal disorders such as ulcers, polyps, colitis, diverticulitis, rhagades, haemorrhoids or cancer. The signs of these lesions are often silent in the first phases, so searching for occult blood in the stool is an important screening test, which allows to identify the presence of pathologies in the gastro-intestinal system at an early stage.

WHO ARE THE INTENDED USERS

Everyone, especially over 45 years.

WHY - BENEFITS

Sometimes, the presence of low quantity of blood in stools is not easily noticeable. In these cases BOWEL FOB TEST is useful to detect the presence of blood in the stools even if they look normal in order to prevent more serious diseases.

TEST PRINCIPLE

BOWEL FOB TEST is an immunochromatographic test that detects the smallest amounts of blood in stool samples by using highly specific monoclonal antibodies. These properties mean that the BOWEL FOB TEST does not require particular dietary restrictions before being carried out.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
40 ng/mL	78,70%	99,00%	92,60%

Performance data obtained by clinical study with 148 participants enrolled. Hb Fecale - Mascia Brunelli kit has been utilized as reference method.

CLINICAL EVIDENCES

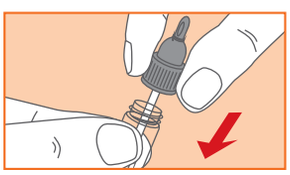
1. Van Rossum Leo G. et al.: "Random Comparison of Guaiac and Immunochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population" Gastroenterology, Volume 135, Issue 1, 82 – 90.
2. Faivre J., Dancourt V., Denis B., Dorval E., Piette C., Perrin P., Bidan J.M., Jard C., Jung S., Levillain R., Viguier J., Bretagne J.F.: "Comparison between a guaiac and three immunochemical faecal occult blood tests in screening for colorectal cancer". European Journal of Cancer. 2012; 48(16):2969-76.
3. Benton S.C., Seaman H.E., Halloran S.P.: "Faecal Occult Blood Testing for Colorectal Cancer Screening: the past or the Future". Current Gastroenterology Reports. 2015; 17(2):428
4. European Commission. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First edition 2010

HOW TO USE IT

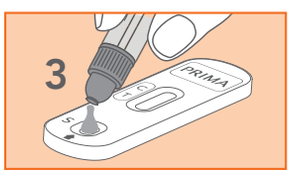
1) Attach the two adhesive surfaces of the stool-collecting sheet on the toilet seat surface.

2) Dip the stick into the faeces in three different points of the sample.

3) Screw on the cap, immersing the stick in the stool extraction liquid, and shake the vial.



4) Break the end of the cap, freeing the dropper portion. Dispense 3 drops of the diluted stool sample in the well shown on the cassette.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 vial with collection stick and dripper, containing the diluent; 1 small sheet for the collection of the stool sample; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800040-1	BOWEL FOB TEST	1 TEST	30 MONTHS

IVD CE 0483

HIV 1/2 SELF-TEST

Rapid self-test for the qualitative detection of antibodies against human immunodeficiency virus 1 and 2 (HIV-1/HIV-2) in whole blood

HIV VIRUS

Human immunodeficiency virus, or HIV, is a pathogen that attacks and suppresses the immune system by specifically affecting white blood cells. Without specific treatment, the virus weakens the subject's immune system to the point of inducing the development of Acquired Immunodeficiency Syndrome, or AIDS. It is a syndrome that can occur in people with HIV even several years after the infection, when the immune system's efficiency dramatically falls, and the body loses its ability to fight even the most common infections.

WHO ARE THE INTENDED USERS

HIV 1/2 SELF-TEST can be used by anyone who has been, or suspects to have been exposed to the virus, people with HIV symptoms or anyone who wants to be aware of a possible infection. Antibody tests can take 23 to 90 days (window period) to detect HIV infection after an exposure.

WHY - BENEFITS

It is very important to support the prevention campaign against HIV, in order to prevent more serious disease, like AIDS, by testing and monitoring the population.

TEST PRINCIPLE

HIV 1/2 SELF-TEST is a rapid immunochromatographic assay, able to specifically detect the presence of antibodies against human immunodeficiency virus 1 and 2 (HIV-1/HIV-2) in whole blood sample.

TECH SPECS

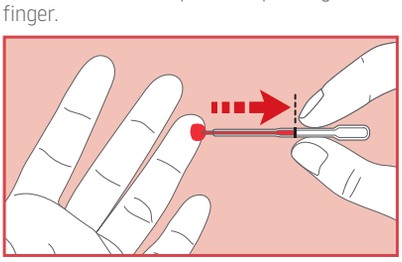
SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
99,30%	99,70%	99,60%

CLINICAL EVIDENCES

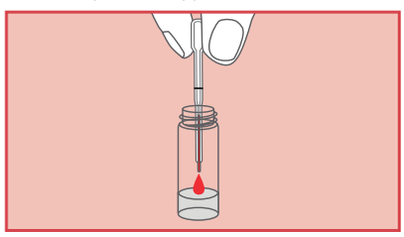
1. https://www.who.int/health-topics/hiv-aids/#tab=tab_1
2. European Centre for Disease Prevention and Control, HIV/AIDS surveillance in Europe (https://www.ecdc.europa.eu/en/all-topics-zhiv-infection-andaidssurveillance-and-disease-data/annual-hivaids-surveillance-reports)
3. https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/symptoms-of-hiv
4. Debit et al., "HIV-1 Group O Genotypes and Phenotypes: Relationship to Fitness and Susceptibility to Antiretroviral Drugs"
5. https://www.cdc.gov/hiv/basics/hiv-testing/test-types.html

HOW TO USE IT

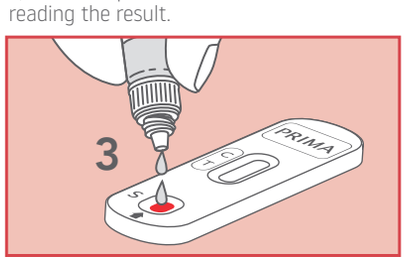
1) Take a blood sample after pricking the finger.



2) Put the blood collected with the pipette into the opened dropper vial.



3) Add 3 drops and wait 10 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

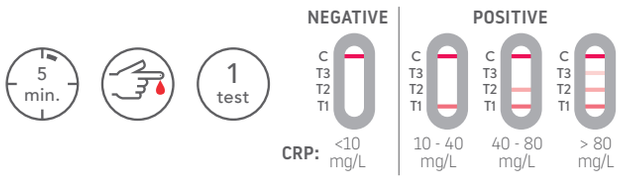
VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800062-1	HIV 1/2 SELF-TEST	1 TEST	24 MONTHS

IVD CE 0483

C-REACTIVE PROTEIN TEST

Rapid self-test for the semi-quantitative detection of C-Reactive Protein (CRP) in whole blood samples



C-REACTIVE PROTEIN

C-Reactive Protein (CRP) is a non specific marker mainly produced by the liver and used to diagnose bacterial diseases and inflammatory disorders. CRP is a very sensitive and fast appearing indicator which could therefore be helpful for deciding an antibiotic treatment.
C-REACTIVE PROTEIN TEST should be performed in case of acute infection symptoms such as feverishness, fever, headaches or weakness.

WHY - BENEFITS

In healthy patients, CRP concentration is lower than 8 mg/L while the concentration level can be higher than 100 mg/L in case of severe infection or during inflammatory process. Intermediate levels, within 8 and 100 mg/L, are concomitant with moåre or less mildly viral or bacterial infections that can be easily overcome by medical treatment. Checking the CRP concentration in blood is useful to verify the presence of possible infections or inflammatory states.

TEST PRINCIPLE

C-REACTIVE PROTEIN TEST is an immunochromatographic assay which detects the CRP level thanks to special monoclonal gold-conjugate antibodies embedded to test strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 mg/L	98,70%	96,00%	97,60%

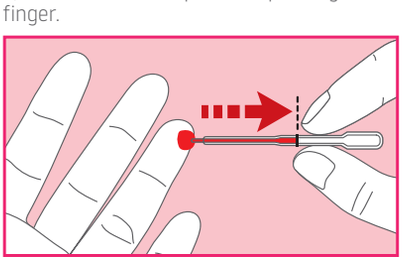
Performance data obtained by clinical study with 127 participants enrolled. Beckam Coulter au680 CRP Latex has been utilized as reference method.

CLINICAL EVIDENCES

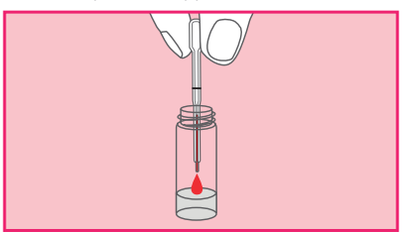
1. THOMPSON, D.; MILFORD-WARD, A.; WHICHER, J. T. „The value of acute phase protein measurements in clinical practice". Annals of clinical biochemistry, 1992, 29.2: 123-131.
2. SHAW, A. C. „Serum C-reactive protein and neopterin concentrations in patients with viral or bacterial infection". Journal of clinical pathology, 1991, 44.7: 596-599
3. C-reactive protein concentrations as a marker of inflammation or infection for interpreting biomarkers of micronutrient status. Vitamin and Mineral Nutrition Information System. Genf: World Health Organization; 2014 (https://www.who.int/nutrition/publications/micronutrients/indicators_c-reactive_protein/en/)
4. https://www.mayoclinic.org/tests-procedures/c-reactive-protein-test/about/pac-20385228

HOW TO USE IT

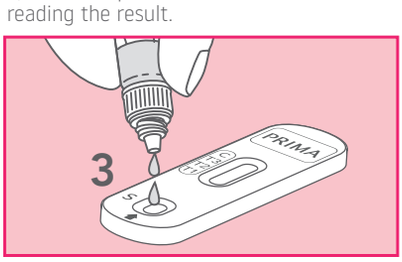
1) Take a blood sample after pricking the finger.



2) Put the blood collected with the pipette into the opened dropper vial.



3) Add 3 drops and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag;, 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800034-1	C-REACTIVE PROTEIN TEST	1 TEST	36 MONTHS

INFECTIOUS DISEASE AREA
THROAT PREVENTION

STREPTOCOCCUS A

Group A ß-hemolytic streptococcus (also known as *Streptococcus pyogenes*) infection of the throat is one of the most common bacterial cause of acute pharyngitis and is also responsible for some skin infections such as impetigo and erysipelas. Most sore throats are caused by viral infections which clear up on their own without antibiotic treatment, which would be useless. While Strep A throat infections sometimes can go away within a few days without treatment, physicians prescribe antibiotics to prevent related complications that can be serious, such as rheumatic fever or acute glomerulonephritis.

WHO ARE THE INTENDED USERS

STREP A TEST can be carried out if there are symptoms such as pain when swallowing, sore throat, red and swollen tonsils, small red patches on the back of the palate, swollen lymph nodes, fever, headache, nausea or vomiting, especially in children.

WHY - BENEFITS

STREP A TEST helps to quickly know whether a sore throat is caused by the bacterium Streptococcus A, which generally requires an antibiotic treatment, or other germs (usually viruses) that do not require this type of treatment.

TEST PRINCIPLE

STREP A TEST is an immunochromatographic test that detects the presence of specific streptococcus A antigens in throat swab samples by using special monoclonal antibodies.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10^4 CFU/mL	91,89%	99,00%	97,90%

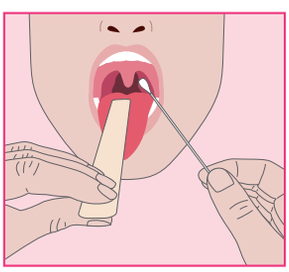
Performance data obtained by clinical study with 238 samples tested comparing with another rapid immunochromatographic test used as reference method.

CLINICAL EVIDENCES

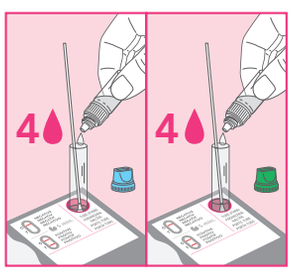
1. Banerjee S, Ford C. "Rapid Tests for the Diagnosis of Group A Streptococcal Infection: A Review of Diagnostic Test Accuracy, Clinical Utility, Safety, and Cost-Effectiveness". Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2018 May. CADTH Rapid Response Reports.
2. Centers for Disease Control and Prevention. Adult appropriate antibiotic use summary. http://www.cdc.gov/getsmart/ community/materials-references/print-materials/hcp/adult-approp-summary.pdf 2016.
3. Llor C., Bjerrum L., Munck A., Cots JM., Hernández S., Moragas A.; HAPPY AUDIT Investigators. "Access to point-of-care tests reduces the prescription of antibiotics among antibiotic-requesting subjects with respiratory tract infections." Respir Care. 2014 Dec.

HOW TO USE IT

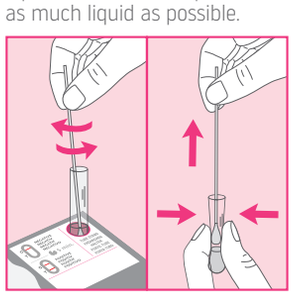
1) Collect a throat sample using the supplied swab and the tongue depressor



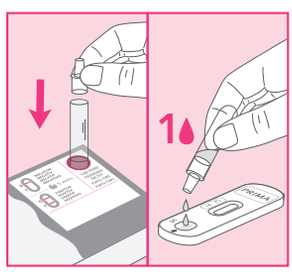
2) Put the swab into the extraction tube inserted in the hole on the back of the package and add the two dilution solutions.



3) Mix the solutions and leave the swab inside the tube for 2-5 minutes. Then remove it and squeeze the cotton tip to collect as much liquid as possible.



4) Apply the dropper to the tube and dispense 1 drop into the well.



CONTENT: 1 hermetically sealed protective aluminium pouche containing: 1 test device and a desiccant bag; 1 sterile swab; 1 sterile wooden tongue depressor; 1 empty plastic test tube for sampling, with dropper; 1 vial with dropper containing the STREP A TEST - R1 solution required for 1 test (blue cap); 1 vial with dropper containing the STREP A TEST - R2 solution required for 1 test (green cap) and 1 instructions for use leaflet.

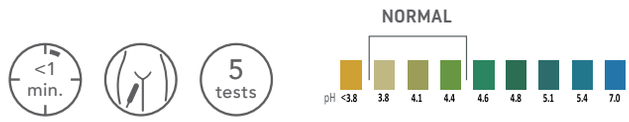
VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800060-1	STREP A TEST	1 TEST	30 MONTHS

IVD CE 0483

VAGINAL PH TEST

Rapid self-test for the semi-quantitative determination of pH in female vaginal swab specimens



VAGINAL INFECTIONS AND pH

Vaginal infections are quite common and often a recurring problem among women of all age groups. An indication of abnormal acidity of the vaginal discharge can help evaluate whether the vaginal symptoms are likely caused by an infection that may require follow-up with an healthcare professional. An acidic vaginal pH value of 3.8 to 4.5 is a basic requirement for the optimal functioning of the body system which protects the vagina. This system can effectively avoid colonization by pathogenic germs and the occurrence of vaginal infections.

WHAT IS VAGINAL pH TEST

VAGINAL pH TEST is a rapid dry chemical method for the semiquantitative detection of pH in female vaginal swab specimens to aid in the diagnosis of bacterial vaginosis.

WHO ARE THE INTENDED USERS

Women who feel vaginal discomfort.

WHY - BENEFITS

Vaginitis is a very common feminine disease affecting million of women each year. Vaginitis accounts for over 50% of all gynaecologic office visits. The key to a proper treatment is an early accurate diagnosis to prevent Bacterial Vaginosis complications.

TEST PRINCIPLE

A pH paper is used to determine pH levels in specimen obtained through a vaginal swab. As soon as the swab containing the specimen from vagina comes in contact with the pH paper encased in the test panel, a colour change occurs. Different pH levels can result in different grades and shades of colour with each colour grade/shade specifying a particular pH level on the colour scale.

TECH SPECS

RANGE OF MEASUREMENT	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
3,80 - 7,00	95,00%	99,00%	98,60%

Performance data obtained by clinical study with 220 participants enrolled. PH Vaginal Rapid Test (pH) has been utilized as reference method.

CLINICAL EVIDENCES

1. Pavletic, A. J., Hawes, S. E., Geske, J. A., Bringe, K., & Polack, S. H. (2004). Experience with routine vaginal pH testing in a family practice setting. Infectious Diseases in Obstetrics and Gynecology, 12(2), 63–68.
2. Huppert, J. S., Hesse, E. A., Bernard, M. C., Bates, J. R., Gaydos, C. A., & Kahn, J. A. (2012). Accuracy and Trust of Self-Testing for Bacterial Vaginosis. The Journal of Adolescent Health : Official Publication of the Society for Adolescent Medicine, 51(4), 400–405.

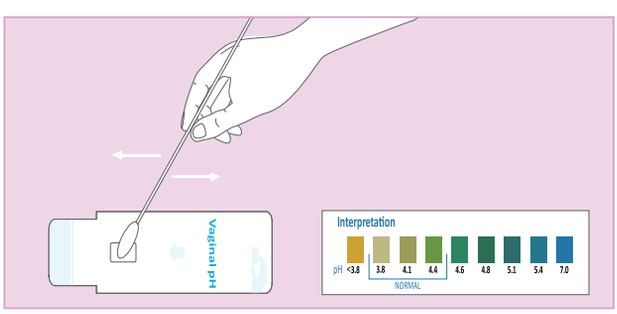
HOW TO USE IT

Insert the head of swab into the vagina and gently press the swab to a point for approximately 10 seconds.

Withdraw the swab from the vagina for testing.

Apply the head of the swab onto the pH area of the Test panel, for at least 5 times.

Read the result immediately while the measurement zone is still wet. Compare the colour in the pH measurement zone with the colour scale on the foil pouch.



CONTENT: 5 sealed aluminum pouches with printed colour scale each containing 1 test device; 5 sterile vaginal swabs; 1 Instructions for use leaflet.

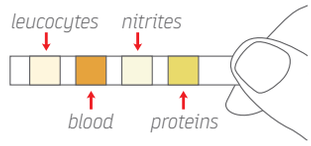
VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100013-5	VAGINAL pH TEST	5 TESTS	24 MONTHS

IVD CE
0483

URINARY TRACT INFECTIONS TEST

Self-test for the detection of leukocytes, blood, nitrites and proteins in urine



URINARY TRACT INFECTIONS

Urinary tract infection (UTI) is a collective term that describes any infection involving any part of the urinary tract, namely the kidneys, ureters, bladder and urethra. It is one of the most common infections in local primary care.

WHO ARE THE INTENDED USERS

The test should be performed in presence of the following symptoms: excessive frequency and/or burning during urination, turbid and/or bad-smelling urine.

WHY - BENEFITS

Checking the presence of urinary tract infections is a useful tool to verify the general health status of the urinary system.

TEST PRINCIPLE

URINARY TRACT INFECTIONS TEST detects the presence of non-physiological levels of leukocytes, blood, nitrites and proteins in urine thanks to specifc chemical reactions which are visibile with a colour change of the reactive area.

TECH SPECS

CUT-OFF	
Leukocytes	9 leu/µL
Blood: free haemoglobin	0,018 mg/dL or 5 Ery/µL
Protein	7,50 mg/dL
Nitrite	0,05 mg/dL

OVERALL ACCURACY	
Leukocytes	97,60%
Blood	96,00%
Protein	88,00%
Nitrite	100,00%

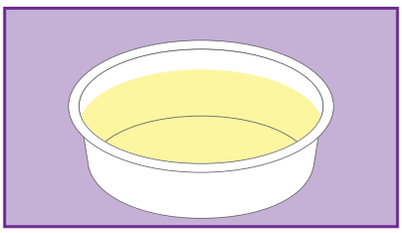
Performance data obtained by clinical study with 125 participants enrolled. U120 Urine Analyser has been utilized as reference method.

CLINICAL EVIDENCES

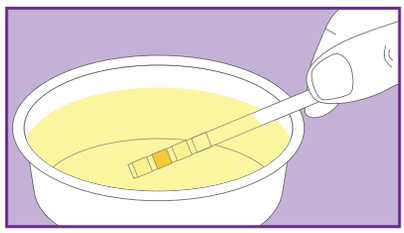
1. Chee Wei Tan, MMed, MCFP1and Maciej Piotr Chlebicki, MBBS, ABIM2: "Urinary tract infections in adults" Singapore Med J. 2016 Sep; 57(9):
2. Copp H.L., Schmidt B.: "Work up of Pediatric Urinary Tract Infection". Urol Clin North Am. 2015 Nov; 42(4): 519–526.

HOW TO USE IT

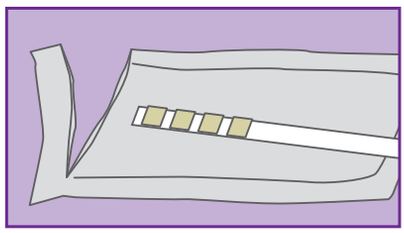
1) The sample is the first urine of the day collected in a clean and dry cup, not provided with the kit.



2) Dip the strip-test for 1-2 seconds.



3) Wait for 2 minutes then check the colours of the strip-test.



CONTENT: 3 sealed aluminium pouches each containing: 1 test strip and 1 desiccant bag; 1 colour chart and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100058-3	URINARY TRACT INFECTIONS TEST	3 TESTS	24 MONTHS

IVD CE 0483

PROSTATE PSA TEST

Self-test for the determination of the Prostate-Specific Antigen (PSA) in whole blood samples

PROSTATE SPECIFIC ANTIGEN (PSA)

The Prostate Specific Antigen (PSA) is a protein produced by the epithelial cells of the prostate gland. Its function is to fluidify the ejaculate and to increase sperm mobility. PSA also plays a role in dissolving cervical mucus, allowing sperm to enter the uterus. Small quantities of PSA are normally found in the blood of men with a healthy prostate. PSA levels may increase with prostate pathologies (prostatitis, benign prostatic hyperplasia etc.), naturally with age or after prostate surgery or specific diagnosis tests (such as rectal examination, prostate biopsy etc.).

WHO ARE THE INTENDED USERS

PROSTATE PSA TEST is intended for:
- men who do not have symptoms, aged over 45, who wish to check their prostate;
- men with urinary tract symptoms (difficulty urinating, pain, increased frequency).

WHY - BENEFITS

Checking the level of the PSA is useful to verify prostate health status. In case of cancer, early detection and prevention can be life saving.

TEST PRINCIPLE

PROSTATE PSA TEST is an immunochromatographic assay which detects the PSA thanks to special monoclonal gold-conjugate antibodies embedded to test strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
4 ng/mL	97,22%	87,13%	92,34%

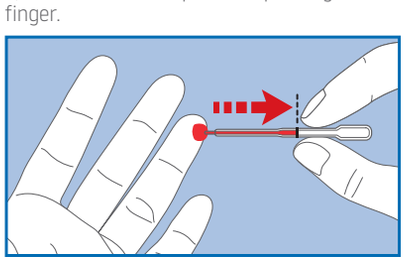
Performance data obtained by clinical study with 209 participants enrolled. Abbott Alinity has been utilized as reference method.

CLINICAL EVIDENCES

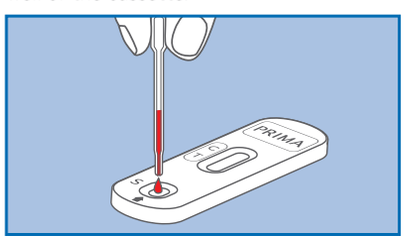
1. Catalona W.J., Southwick P.C., Slawin K.M., Partin A.W., Brawer M.K., Flanigan R.C., Patel A., Richie J.P., Walsh P.C., Scardino P.T., Lange P.H., Gasior G.H., Loveland K.G., Bray K.R.: Comparison of percent free PSA, PSA density, and age-specific PSA cutoffs for prostate cancer detection and staging. Urology. 2000 Aug 1;56(2):255-60.
2. Fritsche H.A., Babaian R.J.: Analytical performance goals for measuring prostate specific antigen. Clin Chem. 1993 Jul;39(7):1525-29.
3. Michael J. Barry, M.D: Prostate-Specific–Antigen Testing for Early Diagnosis of Prostate Cancer. The New England Journal of Medicine, 2001; 344:1373-1377.

HOW TO USE IT

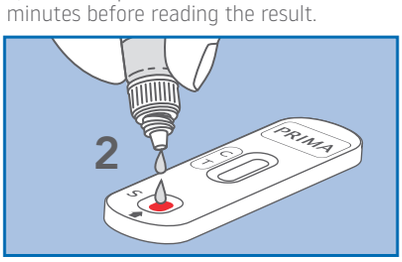
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



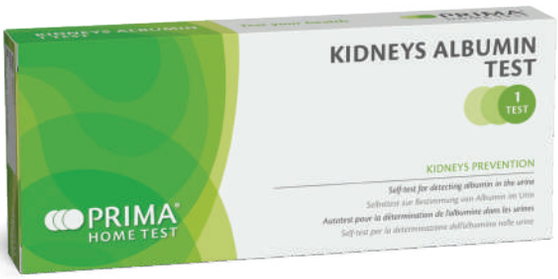
3) Add 2 drops into the well and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800080-1	PROSTATE PSA TEST	1 TEST	30 MONTHS



IVD CE 0483

KIDNEYS ALBUMIN TEST

Self-test for detecting albumin in the urine

5 min. | 1 test

POSITIVE: C T

NEGATIVE: C T | C T

ALBUMIN IN URINE

Albumin is the most abundant plasma protein, formed principally in the liver and constituting up to 2/3 of the 6-8% protein concentration in the plasma. Albumin is responsible for much of the colloidal osmotic pressure of the blood, and thus is very important to regulate the exchange of water between the plasma and the interstitial compartment (i.e. the space between the cells).
The presence of albumin in the urine (albuminuria) may indicate a malfunction of the kidneys and it can accompany kidney disease or heart failure.

WHO ARE THE INTENDED USERS

Everyone who has the suspect of kidney's pathology or with special condition like high blood pressure, diabetes or pregnancy.

WHY - BENEFITS

Checking the presence of albumin protein in urine is useful to verify the general health status.

TEST PRINCIPLE

KIDNEYS ALBUMIN TEST is an immunochromatographic assay which specifically identifies the proteins in human urine and shows if the concentration is equal to or higher than 10 µg/ml.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 µg/mL	96,55%	97,56%	96,97%

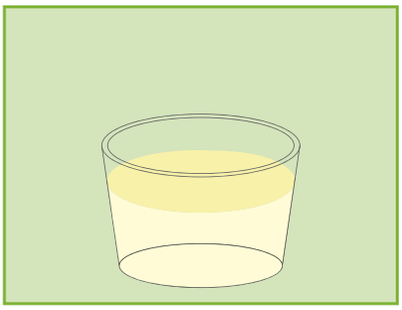
Performance data obtained by clinical study with 99 participants enrolled. Roche Cobas Microalbumin has been utilized as reference method.

CLINICAL EVIDENCES

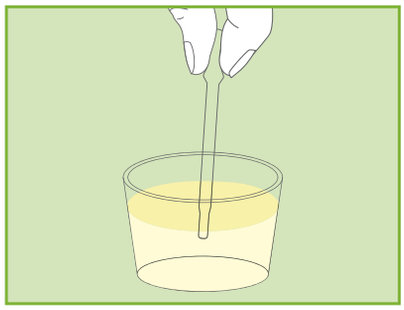
1. Urinary biomarkers of kidney dysfunction. Ann Biol Clin (Paris). 2015 Mar-Apr;73(2):151-7. doi: 10.1684/abc.2015.1029.
2. Lopez-Giacoman, Salvador and Magdalena Madero. "Biomarkers in chronic kidney disease, from kidney function to kidney damage" World journal of nephrology vol. 4,1 (2015): 57-73.
3. Sacks, David B et al. "Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus" Diabetes care vol. 34,6 (2011): e61-99.

HOW TO USE IT

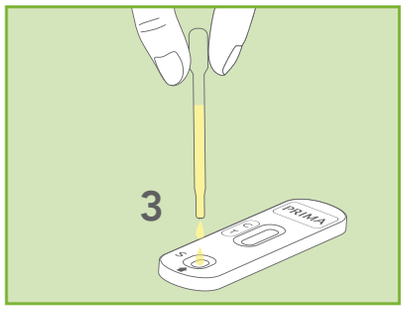
1) The sample is the first urine of the day collected in a clean cup, not provided with the kit.



2) Press the pipette bulb and dip the pipette tip into the collected urine. Release the bulb to collect the urine sample.



3) Deposit 3 drops of sample into the well (S) indicated on the cassette and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test cassette and 1 desiccant bag; 1 plastic pipette for sampling and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
820027-1	KIDNEYS ALBUMIN TEST	1 TEST	36 MONTHS

IVD CE 0483

IRON FER TEST

Self-test for the detection of ferritin levels in whole blood samples

5 min. | 1 test

POSITIVE: C T

NEGATIVE: C T | C T

IRON STORAGE & FERRITIN

Iron is an essential metal for our bodies and is crucial for transporting oxygen in the blood, for cell multiplication and to build the structure of tissues and organs. However, in excessively high levels it is toxic for the body. For this reason, every one of us has a system for taking up iron from the external environment (e.g. via a diet rich in iron-containing foods) and storing it in cells in a way that is not excessive (and therefore not toxic).
Ferritin is the protein responsible for this storage function. The level of ferritin is an excellent indicator of the amount of iron available to the body. Low levels of this protein in the blood are an indication of depleted iron stores, a condition that precedes the development of anaemia. A decrease can be caused by pregnancy, haemorrhages, alterations in iron uptake.

WHO ARE THE INTENDED USERS

Everyone over the puberty age (≈15 years). Before normal levels are higher than the decision value of the cut-off level of this test.

WHY - BENEFITS

Checking the normality of the Ferritin value is a useful tool for verifying the iron deficiency anaemia.

TEST PRINCIPLE

IRON FER TEST is an immunochromatographic assay which detects the protein Ferritin thanks to special monoclonal gold-conjugate antibodies embedded to test strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
30 ng/mL	85,20%	100,00%	96,60%

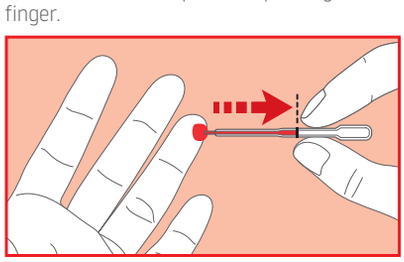
Performance data obtained by clinical study with 120 participants enrolled. Biokit Quantex Ferritin has been utilized as reference method.

CLINICAL EVIDENCES

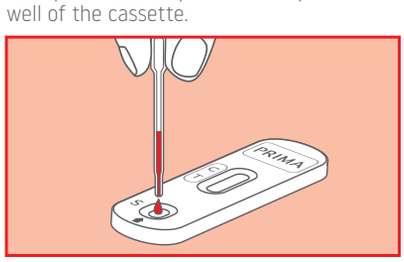
1. Wick M, Pingerra W, Lehmann P, Iron metabolism: diagnosis and therapy of anemias, 5th ed, Vienna, New York: Springer Verlag, 2003; p. 151.
2. Worwood M. The laboratory assessment of iron status – an update. Clin Chim Acta 1997; 259: 3-23.
3. Kaltwasser JP, Werner E. Diagnosis and clinical evaluation of iron overload. Baillieres Clin Haematol 1989; 2; 363-89.
4. Baynes RD, Cook JD. Current issues in iron deficiency. Curr Opin Hematol 1996; 3:145-9.
5. Lee MH, Means RT Jr. Extremely elevated serum ferritin levels in a university hospital: associated diseases and clinical significance. Am J Med 1996; 98: 566-71.

HOW TO USE IT

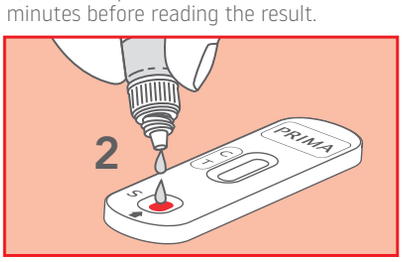
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



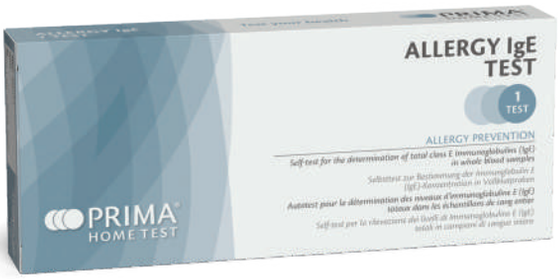
3) Add 2 drops into the well and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800025-1	IRON FER TEST	1 TEST	30 MONTHS



IVD CE 0483

ALLERGY IgE TEST

Self-test for the determination of total class E Immunoglobulins (IgE) in whole blood samples

5 min. | 1 test

POSITIVE | NEGATIVE

ALLERGIES AND IgE

Immunoglobulins E (IgE) are the class of antibodies that are most involved in allergic reactions. In normal conditions, IgE are present in blood in a really low quantity.
However, when they come in contact with the allergens, their concentration increases and they can trigger the cascade of reactions leading to the appearance of the main symptoms of an allergic reaction (such as skin erythema, itchiness, sneezing repeatedly, and, in some cases, anaphylactic shock).
This is why it is important to check if IgE levels are above normal, especially in people with a family history of allergies.

WHO ARE THE INTENDED USERS

ALLERGY IgE TEST is recommended to everyone with allergic reaction symptoms, such as itching and/or reddened skin, watery eyes and sneezing repeatedly.

WHY - BENEFITS

Checking the presence of IgE antibodies is useful to verify a potential general allergy reaction.

TEST PRINCIPLE

ALLERGY IgE TEST is an immunochromatographic test that detects the presence of IgE antibodies in the blood in concentrations above average, using special monoclonal antibodies conjugated with gold and integrated into the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
100 IU/mL	93,42%	91,42%	92,46%

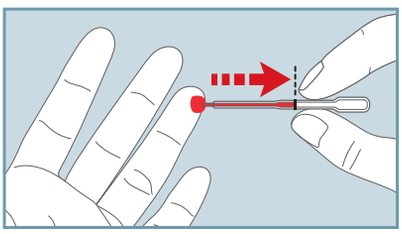
Performance data obtained by clinical study with 146 participants enrolled. Immunocap Total IgE Thermofisher has been utilized as reference method.

CLINICAL EVIDENCES

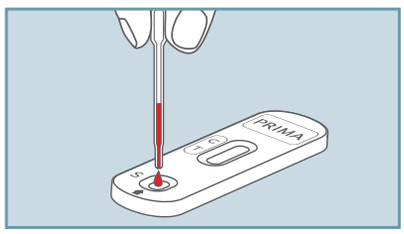
1. Martins T.B., Bandhauer M.E., Bunker A. M., Roberts W. L.: "New childhood and adult reference intervals for total IgE." Journal of Allergy and Clinical Immunology. 2014;133(2):589-91.
2. Chang M.L., Cui C., Liu Y.H., Pei L.C., Shao B.: "Analysis of total immunoglobulin E and specific immunoglobulin E of 3,721 patients with allergic disease". Biomed Rep. 2015 Jul;3(4):573-577.
3. I. Leonard Bernstein, MD; James T. Li, et Al.: "Annals of allergy, asthma, & immunology." March 2008; Vol 100, num 3, supplement 3.

HOW TO USE IT

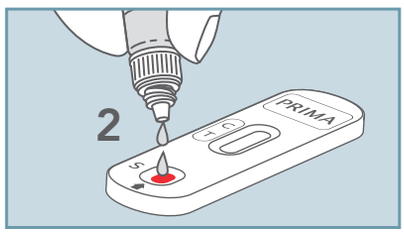
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800018-1	ALLERGY IgE TEST	1 TEST	36 MONTHS

IVD CE
0483

VITAMIN D TEST

Rapid self-test for the semi-quantitative detection of Vitamin D in human whole blood

10 min. | 1 test

- **DEFICIENT** 0-10 (ng/mL) 0-25 (nmol/L)
- **INSUFFICIENT** 10-30 (ng/mL) 25-75 (nmol/L)
- **SUFFICIENT** 30-100 (ng/mL) 75-250 (nmol/L)
- **EXCESS** >100 (ng/mL) >250 (nmol/L)

VITAMIN D

Vitamin D refers to a group of fat-soluble secosteroids responsible for increasing intestinal absorption of calcium, iron, magnesium, phosphate and zinc. Vitamin D is produced by skin exposed to ultraviolet B radiation or obtained from dietary sources, including supplements. Average daily vitamin D intake in the population and current dietary reference intake values are often inadequate to maintain optimal vitamin D levels. Virtually every cell in our body has receptors for Vitamin D, meaning that they all require "sufficient" level of Vitamin D for adequate functioning. Vitamin deficiency has been linked to various serious diseases: osteoporosis, multiple sclerosis, cardiovascular diseases, pregnancy complications, diabetes, strokes, autoimmune diseases, infectious diseases, etc.

WHO ARE THE INTENDED USERS

VITAMIN D TEST is intended for persons commonly at risk for vitamin D deficiency, such as people who get: tired and fatigued easily, inadequate sun exposure, limited oral intake, or have impaired intestinal absorption.

WHY - BENEFITS

VITAMIN D TEST helps understanding whether Vitamin D levels are sufficient, insufficient or deficient, allowing the person to take precautions in time.

TEST PRINCIPLE

VITAMIN D TEST is an immunochromatographic assay that, thanks to specific antibodies, is able to detect the levels of 25-hydroxyvitamin D in blood sample and to highlight its concentration thanks to the intensity of the test line (T) obtained.

TECH SPECS

CUT-OFF	RANGE OF MEASUREMENTS	OVERALL ACCURACY
30 ng/mL	10-100 ng/mL	94,40%

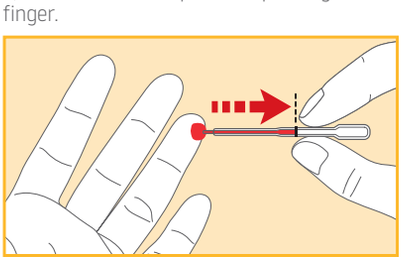
Performance data obtained by comparing the test with another EC marked Vitamin D Rapid Test.

CLINICAL EVIDENCES

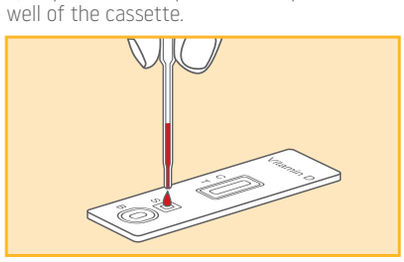
1. Grant WB, Holick MF (June 2005). Benefits and requirements of vitamin D for optimal health: a review. Alternative Medicine Review.10 (2): 94–111.
2. Moyad MA. Vitamin D: a rapid review. DermatolNurs. 2009, 21:25-30
3. Holick MF (March 2006). "High prevalence of vitamin D inadequacy and implications for health". Mayo Clinic Proceedings. 81 (3): 353–73.

HOW TO USE IT

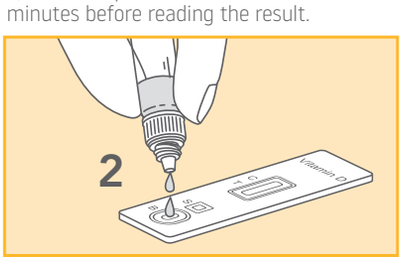
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 10 minutes before reading the result.



CONTENT: 1 sealed aluminum pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collection; 1 vial containing the diluent; 1 color card; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100066-1	VITAMIN D TEST	1 TEST	24 MONTHS

DRUG TEST

Self-test for the detection of 6 drugs in urine: Morphine, Amphetamine, Cocaine, Marijuana, Methamphetamine and Methadone

DETECTED SUBSTANCES

TEST	Cut-off (ng/mL)	Time permanence in urine after exposure
Amphetamine (AMP1000)	1000	1-3 days for a single administration, up to 9 days in chronic users
Cocaine (COC 300)	300	1-3 days for a single administration, up to 3 weeks in chronic users
Marijuana	50	single administration (smoking): 30 h on average, up to 4 days single administration (oral intake): up to 6 days occasional use (once or twice a week): up to 30 days regular consumption: up to 3 months
Methadone (MTD 300)	300	1,5 to 3 days
Methamphetamine (MET 500)	500	1 to 4 days for a single administration, up to 5 days in chronic users
Morphine (MOP 300)	300	10-55 h for a single administration, up to 11 days in chronic users

WHO ARE THE INTENDED USERS

DRUG TEST can be used by everyone who wants to check the presence of the above mentioned substances in urine.

TEST PRINCIPLE

DRUG TEST is an immunochromatographic assay that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect levels of specific drugs in urine.

TECH SPECS

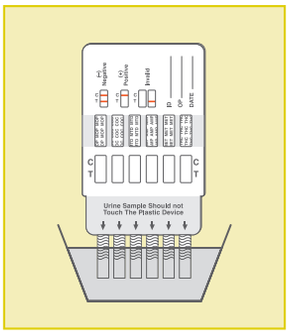
	CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
AMP	1000 ng/mL	99,90%	99,90%	99,90%
MET	500 ng/mL	99,90%	99,90%	99,90%
COC	300 ng/mL	99.30%	99,90%	99,70%
MOP	300 ng/mL	99,90%	99,40%	99,70%
MTD	300 ng/mL	99,30%	99,90%	99,70%
THC	50 ng/mL	99,90%	99,40%	99,70%

HOW TO USE IT

1) Open the cap, with the arrow pointing toward the urine specimen, dip the test panel vertically in the urine specimen for at least 10 to 15 seconds.

2) Replace the cap and leave the test panel on a non-absorbent flat surface.

3) Wait 5 minutes before reading the result.



CONTENT: 1 sealed aluminium pouch containing: 1 test panel and 1 desiccant bag; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
19806-1	DRUG TEST	1 TEST	24 MONTHS

IVD CE 0483

EARLY PREGNANCY TEST

Rapid self-test for the early detection of the hCG in human urine samples (10 mIU/mL)

5 min. | 1-2 test

POSITIVE T C | NEGATIVE T C

PREGNANCY AND hCG

In the very early stages of pregnancy, the fertilized egg is transported from the tubes to the uterus where, around seven days later, it lurks. Precisely at this stage, the tissue that will form the placenta begins to produce the human Chorionic Gonadotropin, also called hCG hormone, essential for the correct development of pregnancy.
The quick appearance and rapid increase in the concentration of the hCG hormone in the urine make it an excellent indicator for the early confirmation of pregnancy.

WHO ARE THE INTENDED USERS

Women who want to identify early stages of pregnancy.

WHY - BENEFITS

The test detects the hCG hormone in urine at a concentration of 10 mIU/mL, therefore the test can be performed 3 days before the period is due. So in this way it is possible to early identify a pregnancy.

TEST PRINCIPLE

EARLY PREGNANCY TEST is an immunochromatographic assay for the early detection of hCG hormone in urine by using a combination of one monoclonal-dye conjugate and another one monoclonal-solid phase antibody to selectively identify hCG in test samples.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 mIU/mL	100%	100%	100%

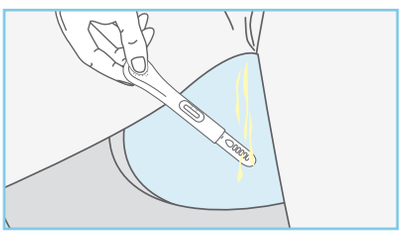
Performance data obtained by clinical study with 47 participant enrolled. Clearblue Test Early Pregnancy has been used as reference method.

CLINICAL EVIDENCES

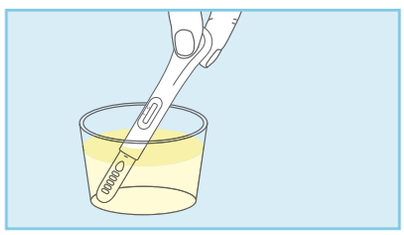
1. Batzer FR. "Hormonal evaluation of early pregnancy", Fertil. Steril. 1980; 34(1): 1-13 2.
2. Snjder J.A., Haymonth F., Parvin C.A. et al. "Diagnostic considerations in the measurement of Human
Chorionic Gonadotrophin in aging women" Clin Chem 2005; 51: 1830 – 1835
3. Gnoth C., Johnson S.: "Strips of hope: accuracy of home pregnancy tests and new development"

HOW TO USE IT

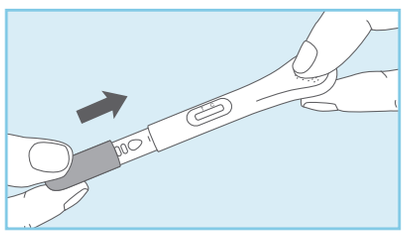
1) Remove the protective cap and place the absorbing tip right under the flow of urine for at least 10 seconds.



2) If easier, collect the urine in a clean, dry, residue-free container and dip the absorbing tip into the urine for 10 seconds.



3) Place the protective cap back onto the absorbing tip.Wait 5 minutes before reading the result.



CONTENT: 1 or 2 sealed aluminium pouches containing each: 1 spoon device and 1 desiccant bag; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
820010-1	EARLY PREGNANCY TEST	1 TEST	36 MONTHS
820010-2	EARLY PREGNANCY TEST	2 TESTS	

IVD CE 0483

OVULATION LH TEST

Self-test for the detection of luteinizing hormone (LH) in urine

5 min. | 5 tests

POSITIVE: T C | NEGATIVE: T C

LH AND OVULATION

During the entire childbearing age, the period of time between puberty and menopause, women reproductive system meets monthly a series of structural and functional important changes. This happens because of the continuous changes in estrogen levels and progesterone, hormones that are regulated by the Hypothalamus-Hypophysis-Ovary axis. Their concentrations are different during the 4 phases of menstrual cycle: menstruation, follicular phase, ovulation and luteal phase. During the ovulation phase, which occurs around the 12th/13th day of the menstrual cycle, the level of estrogen in the blood is so high that the hypophysis starts the production ofthe Luteinizing Hormone (LH), thus determining the breakdown of the follicle and the release of the egg cell, ready to be fertilized. The egg cell remains fertilizable up to the next 24 hours.

WHO ARE THE INTENDED USERS

Women who want to conceive.

WHY - BENEFITS

Measuring the levels of hormone LH in the urine is an effective method to optimize the possibility of conception.

TEST PRINCIPLE

OVULATION LH TEST is an immunochromatographic assay that detects LH through special goldconjugated monoclonal antibodies included in the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
25 mIU/mL	100,00%	97,14%	98,11%

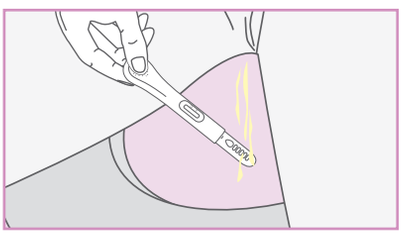
Performance data obtained by clinical study with 53 participants enrolled. iXensor Ovulation LH test (Immunochromatographic Lateral Flow) has been utilized as reference method.

CLINICAL EVIDENCES

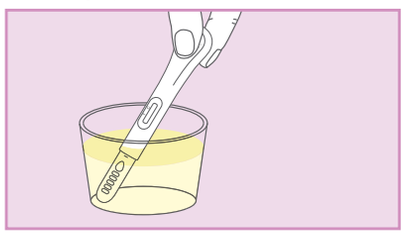
1. Su HW, Yi YC, Wei TY, Chang TC, Cheng CM "Detection of ovulation, a review of currently available method" Bioeng Transl Med. 2017 May 16;2(3):238-246.
2. Leiva RA, Bouchard TP. Abdullah SH, Ecochard R.: "Urinary Luteinizing Hormone Tests: Which concentration threshold best predict ovulation?" Front public health 2017, 5: 320.

HOW TO USE IT

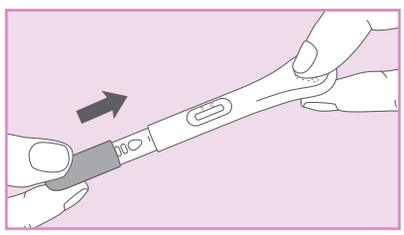
1) Remove the protective cap and place the absorbing tip right under the flow of urine for at least 10 seconds.



2) If easier, collect the urine in a clean, dry, residue-free container and dip the absorbing tip into the urine for 10 seconds.



3) Place the protective cap back onto the absorbing tip.Wait 5 minutes before reading the result.



CONTENT: 5 sealed aluminium pouches containing each: 1 spoon device and 1 desiccant bag; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
820050-5	OVULATION LH TEST	5 TESTS	30 MONTHS

IVD CE 0483

MENOPAUSE FSH TEST

Self-test for the determination of the Follicle Stimulating Hormone - FSH in urine

5 min. | 2 tests

POSITIVE: T C

NEGATIVE: T C

MENOPAUSE AND FSH

Menopause is defined as the time when there has been no menstrual periods for 12 consecutive months and no other biological or physiological cause can be identified. The menopause is caused by a modification of the hormonal balance in woman's body. This change arises generally when close to 45 years old. But true signs are observed around 55 years old. An irregular duration of periods is an early indication of the menopause beginning (peri-menopause). Menopause is the consequence of the end of ovary follicle life-cycle leading to increase of Follicle Stimulating Hormone (FSH) circulating level. Concentration of FSH increases during menopause passing from values less than 20 mUI/mL up to approximately 80 mUI/mL.

WHO ARE THE INTENDED USERS

WOMEN > 45 years.

WHY - BENEFITS

Checking the presence of high levels of FSH is a useful tool for verifying a potential ongoing menopause status.

TEST PRINCIPLE

MENOPAUSE FSH TEST is an immunochromatographic test that detects FSH through special goldconjugated monoclonal antibodies included in the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
25 mIU/mL	100,00%	86,90%	94,00%

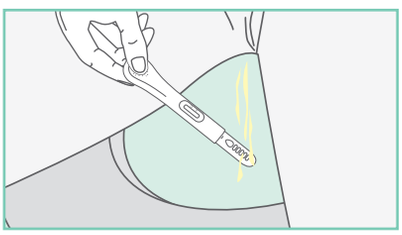
Performance data obtained by clinical study with 100 participants enrolled. Roche Cobas 8000 has been utilized as reference method.

CLINICAL EVIDENCES

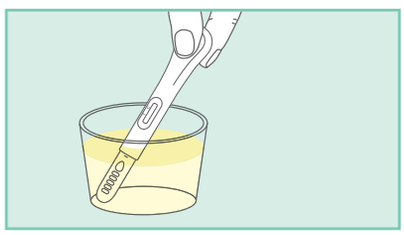
1. Robert J. Norman "Fertility testing" Australian Prescriber, 2002;25:38-401
2. Buckler H. "The menopause transition: endocrine changes and clinical symptoms." J Br Menopause Soc. 2005 Jun;11(2):61-5.
3. National Collaborating Centre for Women's and Children's Health (UK) "Menopause: Full Guideline". 2015 Nov. National Institute for Health and Care Excellence: Clinical Guidelines.

HOW TO USE IT

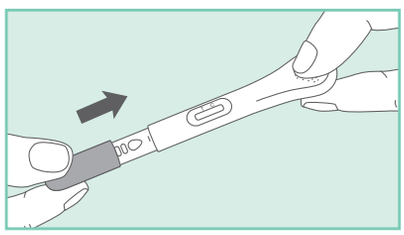
1) Remove the protective cap and place the absorbing tip right under the flow of urine for at least 10 seconds.



2) If easier, collect the urine in a clean, dry, residue-free container and dip the absorbing tip into the urine for 10 seconds.



3) Place the protective cap back onto the absorbing tip.Wait 5 minutes before reading the result.



CONTENT: 2 sealed aluminium pouches containing each: 1 spoon device and 1 desiccant bag; 1 instructions for use leaflet.

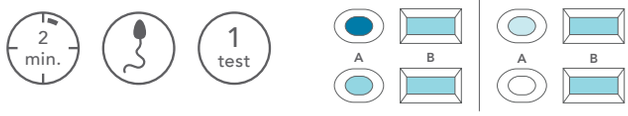
VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
820011-2	MENOPAUSE FSH TEST	2 TESTS	30 MONTHS

IVD CE
0483

SPERM TEST

Rapid self-test for in-vitro qualitative estimation of sperm concentration in human semen



MALE INFERTILITY

Male infertility can be an health issue for men and is primarily responsible for inability to conceive after 1 year of regular, unprotected intercourses. Particularly, male factor infertility affects nearly 50% of infertile worldwide couples who want to conceive and to require empirical therapy. Sperm count is considered lower than normal if you have fewer than 15 million sperm per milliliter of semen.

WHAT IS SPERM TEST

SPERM TEST is designed to be used for in vitro qualitative estimation of the sperm concentration of human semen. The test will determine if the number of sperms is adequate for conception, subject to female partner's ovulation in time. A low sperm concentration would indicate less likelihood of conception.

WHO ARE THE INTENDED USERS

Men who want to check their sperm concentration.

WHY - BENEFITS

Checking the sperm concentration is a useful tool for verifying the male fertility status.

TEST PRINCIPLE

SPERM TEST is biochemical assay for in vitro qualitative estimation of sperm concentration in human semen. Sperm cells are trapped on the first surface layer of the membrane, while a staining solution is used to dye sperm cells. The darker is the colour of well A, the higher is the sperm concentration. If the colour of well A is lighter than the standard colour of reference well B, it means that the concentration of sperm is less than 15 million/mL. If the colour of well A test is darker than the standard colour of reference well B, it means that the sperm concentration is greater than 15 million/mL.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
15 million/mL	98,10%	99,50%	99,10%

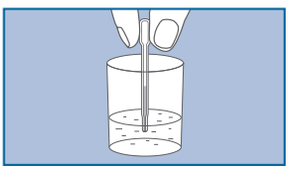
Performance data obtained by clinical study with 236 participants enrolled. Sperm Concentration Rapid Test (Colorimetric) has been utilized as reference method.

CLINICAL EVIDENCES

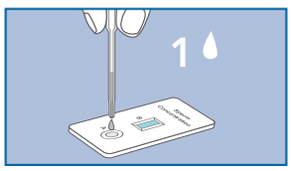
1. Centola G.M.: Semen assessment. Urol Clin North Am. 2014 Feb;41(1):163-7. doi: 10.1016/j.ucl.2013.08.007. Epub 2013 Sep 13.
2. Cooper T.G., Noonan E., von Eckardstein S., Auger J., Baker H.W., Behre H.M., Haugen T.B., Kruger T., Wang C., Mbizvo M.T., Vogelsong K.M. World Health Organization reference values for human semen characteristics. Hum Reprod Update. 2010 May-Jun;16(3):231-45.

HOW TO USE IT

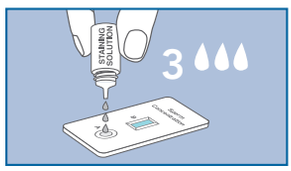
1) Collect the semen directly into the collection cup. Shake it evenly in the collection cup and leave it to stand for 15 minutes until the semen liquefies.



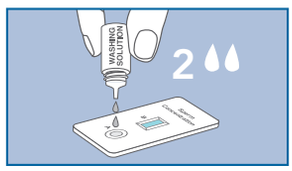
2) Using the provided pipette, dispense one drop of semen into test well A.



3) Add three drops of the blue staining solution to well A. Let it soak for 1-2 minutes.



4) Apply two drops of the transparent washing solution to well A, and let it soak for 1-2 minutes, then read the results immediately by comparing the colour of A to B.



CONTENT: 1 sealed aluminium pouch containing: 1 test device, 1 desiccant bag and 1 pipette; 1 vial with dropper tip containing the staining solution; 1 vial with dropper tip containing the washing solution; 1 collection cup and 1 instructions for use leaflet.

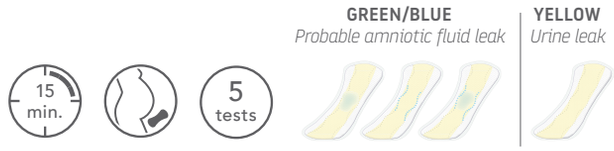
VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100082-1	SPERM TEST	1 TEST	24 MONTHS

IVD CE 0483

AMNIOCHECK

Amniotic leak self-test detector



TEST PRINCIPLE

AMNIOCHECK changes colours when it comes in contact with fluid of pH levels greater than or equal to 6,5 units. Amniotic fluid pH levels are greater than 6,5.
The panty liner is specific to vaginal fluid, and if contaminated with urine, in the range of pH 5,5-7,0, will not give a positive result (combination of the chemical formulation and panty liner composition reduces interference from urine and therefore increase specificity).

WHAT IS AMNIOCHECK

AMNIOCHECK is designed to detect any minute (100 microlitre) leak of amniotic fluid, differentiating it from urine by detecting the pH level.

WHO ARE THE INTENDED USERS

- Gynecologists' clinics or Delivery rooms:
  for amniotic fluid leakage screening or verification, especially for non-continuous leakage.
- Pregnant women at home:
  women with normal pregnancies experiencing unexplained wetness as well as by those at high risk of Premature Rupture of Membrane (PROM) and Preterm Premature Rupture of Membrane (PPROM).

Availabe for home use and prefessional use.

WHY - BENEFITS

Non invasive method, easy to use; early diagnosis of PROM and PPROM; reduction of unnecessary speculum examination; reduction of time spent in hospital; reduced risk of infection from speculum examination (particularly if repeat examinations are required); incidental detection of possible vaginal infection; reduction in staff time and hospital bed use.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
pH > 6,5	97,10%	96,90%	PPV 96,10% NPV 97,67%

Performance data obtained by clinical studies conducted in 2016-2017 (5 American centres and 1 Israelian centre) with 232 pregnant women enrolled. AMNIOCHECK has been compared to the standard clinical diagnosis protocol.

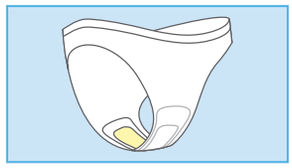
CLINICAL EVIDENCES

The National Institute for Health and Care Excellence (NICE, UK) has conducted evaluated this panty liner as "sufficiently accurate to exclude amniotic fluid leak as a cause of wetness in pregnancy, [...] the use of the panty liner could generate costs savings and avoid the discomfort of unnecessary speculum examinations, [...] its use should be encouraged."

Bibliography:
1) Bornstein J, Geva A, Salt I, Fait V, Schoenfeld A, Shoham HK, Sobel J. Nonintrusive diagnosis of premature ruptured amniotic membranes using a novel polymer. Am J Perinatol. 2006 Aug; 23(6):351-4.
2) Bornstein J, Ohel G, Sorokin Y, Reape KZ, Shnaider O, Kessary-Shoham H, Ophir E. Effectiveness of a novel home-based testing device for the detection of rupture of membranes. Am J Perinatol. 2009 Jan;26(1):45-50.

HOW TO USE IT

Attach the panty liner to the underwear; the panty liner has a central polymer-embedded strip that turns blue-green on contact with fluid. Wear the panty liner as a normal panty liner till feel wetness (do not exceed 12 hours). At the first sense of vaginal wetness, remove the panty liner and wait up to 15 minutes and check for a colour change on the panty liner.
The detection panty liner is specific to vaginal fluid, and if contaminated with urine it will not give a positive result.



CONTENT: 5 aluminum pouches containing 1 panty liner each; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100088-5	AMNIOCHECK	5 TESTS	48 MONTHS

GIARDIA PET TEST

Rapid test for the qualitative identification of Giardia lamblia antigens in animal faeces

10 min. | 1 test

POSITIVE | NEGATIVE

GIARDIA

Giardia lambia is a microscopic protozoan contracted by oral ingestion. It attacks the inner wall of animal's small intestine and interferes with the normal fats and carbohydrates absorption during digestion.

WHO ARE THE INTENDED USERS

GIARDIA PET TEST is recommended to everyone who wants to check their pet's health status. More common symptoms are: nausea, diarrhea, fever and weight loss.

WHY - BENEFITS

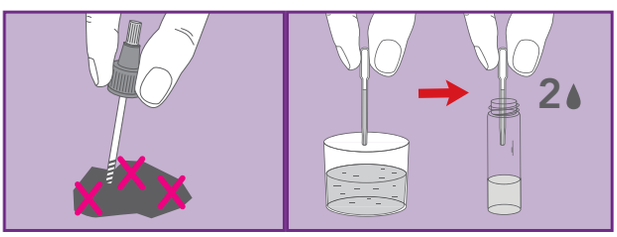
It is important to diagnose Giardiasis as soon as possible. The disease, if not treated, can lead to chronic debilitation with anorexia, progressive culling, slimming and growth retardation.

TEST PRINCIPLE

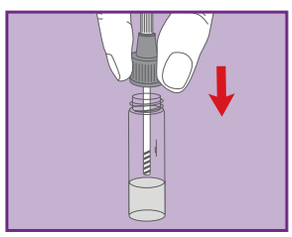
Giardia Test is a lateral flow immunochromatographic assay which detects the Giardia antigen using highly specific monoclonal antibodies.

HOW TO USE IT

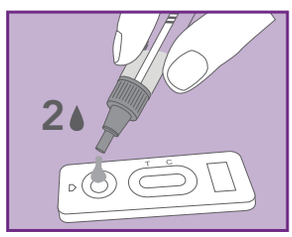
1) Collect the sample and dip the stick into feces in different points.



2) Put the stick in the stool extraction liquid and shake the vial.



3) Apply 2 drops of the diluent stool sample. Wait 10 minutes and read the result.



CONTENT: 1 sealed aluminum pouch containing: 1 GIARDIA PET TEST and 1 desiccant bag; 1 transparent plastic bag containing a pipette for specimen collection; 1 vial with green screw cap with collection stick and dripper; instructions for use.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
PET100-1	GIARDIA PET TEST	1 TEST	24 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

STREP A RAPID TEST

Rapid Test for the detection of group A β-hemolytic Streptococcus in pharyngeal swab

5 min.

20 tests

POSITIVE

NEGATIVE

STREPTOCOCCUS A

Group A ß-hemolytic streptococcus (also known as *Streptococcus pyogenes*) is a Gram-positive bacterium that constitutes the most frequent bacterial cause of acute pharyngitis - 30/40% in European children and 5-15% in adults.
In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to quickly identify the pathological agent.

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present the following symptoms: sore throat, pain when swallowing, red and swollen tonsils, fever, weakness, nausea and vomit (especially in children). It's important to pay higher attention to children (higher incidence between 3-15 yrs) and fragile people (e.g. elderly persons).

TEST PRINCIPLE

STREP A RAPID TEST is a rapid lateral flow immunochromatographic assay for the qualitative detection of specific streptococcus A antigens in human throat swab, thanks to special gold conjugate antibodies embedded to a test strip.

TECH SPECS

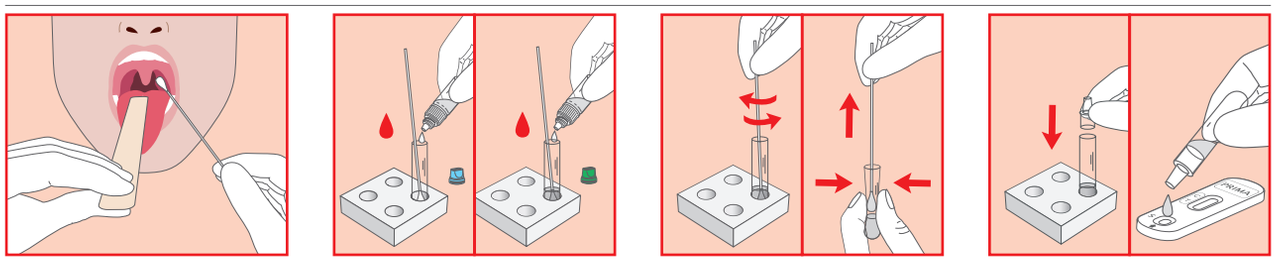
CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10^4 CFU/mL	91,89%	99,00%	97,90%

Performance data obtained by clinical study with 238 samples tested comparing with another rapid immunochromatographic test used as reference method.

CLINICAL EVIDENCES

1. Banerjee S, Ford C. "Rapid Tests for the Diagnosis of Group A Streptococcal Infection: A Review of Diagnostic Test Accuracy, Clinical Utility, Safety, and Cost-Effectiveness". Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2018 May. CADTH Rapid Response Reports.
2. Centers for Disease Control and Prevention. Adult appropriate antibiotic use summary. http://www.cdc.gov/getsmart/ community/materials-references/print-materials/hcp/adult-approp-summary.pdf 2016.
3. Llor C., Bjerrum L., Munck A., Cots JM., Hernández S., Moragas A.; HAPPY AUDIT Investigators. "Access to point-of-care tests reduces the prescription of antibiotics among antibiotic-requesting subjects with respiratory tract infections." Respir Care. 2014 Dec.

HOW TO USE IT



CONTENT: 20 test cassettes, 20 swabs, 20 tongue depressors, 20 empty test tubes with droppers, 1 R1 vial, 1 R2 vial, 1 workstation, 1 instruction for use.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800060IP-20P	STREP A RAPID TEST	20 TESTS	30 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

C-REACTIVE PROTEIN RAPID TEST

Rapid test for the semi-quantitative detection of C-Reactive Protein (CRP) in whole blood or serum samples

C-REACTIVE PROTEIN

C-Reactive Protein (CRP) is an acute phase protein mainly produced by the liver, whose concentration increases following injuries, infections and inflammation.
The levels of CRP in the blood are high during bacterial infections (> 80 mg/L), while they low down during viral infections. For this reason, the measurement of CRP can be a useful tool for defining the cause of an inflammatory state. Worldwide, CRP testing reduced by 20% antibiotic prescription.

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present the following symptoms: weakness, fever and headache. It is also a useful tool to monitor the progress of post-surgery therapies.

TEST PRINCIPLE

C-REACTIVE PROTEIN RAPID TEST is a rapid lateral flow immunochromatographic assay for the semi-quantitative detection of CRP in human whole blood, thanks to special gold conjugate antibodies embedded to a test strip with three different test lines.

TECH SPECS

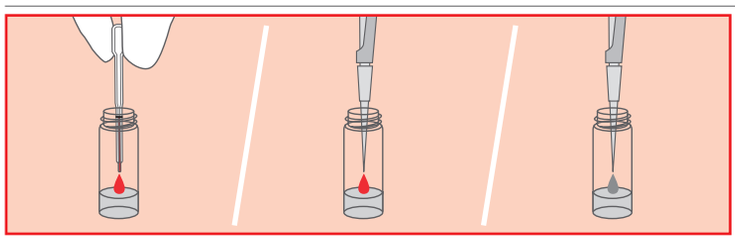
CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 mg/L	98,70%	96,00%	97,60%

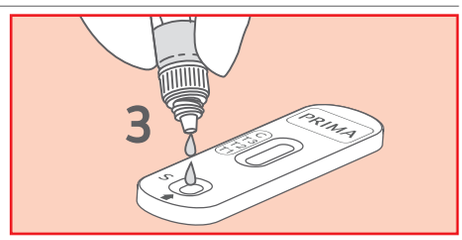
Performance data obtained by clinical study with 127 participants enrolled. Beckam Coulter au680 CRP Latex has been utilized as reference method.

CLINICAL EVIDENCES

1. C-reactive protein concentrations as a marker of inflammation or infection for interpreting biomarkers of micronutrient status. Vitamin and Mineral Nutrition Information System. Geneva: World Health Organization; 2014 (WHO/NMH/NHD/EPG/14.7).
2. Calarco et al. 2023. "Analytical Performance of 17 Commercially Available Point-of-Care Tests for CRP to Support Patient Management at Lower Levels of the Health System." PLOS ONE 18 (1): e0267516.
3. Dittrich et al. (2016) "Target Product Profile for a Diagnostic Assay to Differentiate between Bacterial and Non-Bacterial Infections and Reduce Antimicrobial Overuse in Resource-Limited Settings: An Expert Consensus". PLoS ONE 11(8): e0161721. doi:10.1371/journal.pone.0161721.
4. Martínez-González et al. 2020. "Point-of-Care C-Reactive Protein Testing to Reduce Antibiotic Prescribing for Respiratory Tract Infections in Primary Care: Systematic Review and Meta-Analysis of Randomised Controlled Trials." Antibiotics (Basel, Switzerland) 9 (9): 610.

HOW TO USE IT





CONTENT: 20 test cassettes; 20 pipettes; 20 vials with diluent; 1 instructions for use leaflet.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800034IP-20P	C-REACTIVE PROTEIN RAPID TEST	20 TESTS	36 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

VITAMIN D RAPID TEST

Rapid test for the semi-quantitative detection of 25-hydroxy vitamin D in human whole blood

10 min.

20 tests

DEFICIENT
0-10 (ng/mL) 0-25 (nmol/L)

INSUFFICIENT
10-30 (ng/mL) 25-75 (nmol/L)

SUFFICIENT
30-100 (ng/mL) 75-250 (nmol/L)

EXCESS
>100 (ng/mL) >250 (nmol/L)

VITAMIN D

Vitamin D refers to a group of fat-soluble secosteroids responsible for increasing intestinal absorption of calcium, iron, magnesium, phosphate and zinc. It's an essential element, involved in many biological processes, both produced by the skin (vitamin D3) or intaken with diet (vitamin D2 and D3). Vitamin D is metabolized by the liver as 25-hydroxy-vitamin D.
Average daily vitamin D intake is often inadequate to maintain optimal levels leading to potential diseases: many countries worldwide report very high prevalence of vitamin D status (24% in US and 40% in EU).

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who are suffering from osteoporosis, diabetes and immune disease. In addition to anyone who easily gets tired and gets inadequate sun expore and limited oral intake. It's also useful to prevent deficiency-related conditions, personalizing treatments and supplementation and monitoring food supplements intake.

TEST PRINCIPLE

VITAMIN D RAPID TEST is a rapid lateral flow immunochromatographic assay for the semi-quantitative detection of 25-hydroxy vitamin D (25 (OH) D) in human whole blood, thanks to special gold conjugate antibodies embedded to a test strip.

TECH SPECS

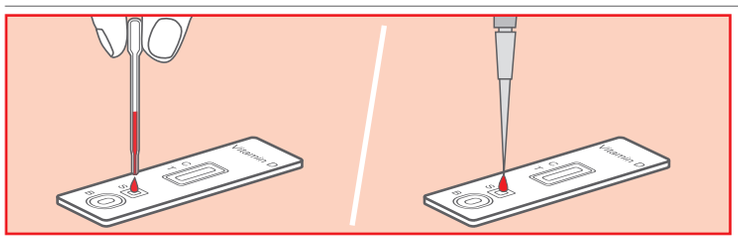
CUT-OFF	RANGE OF MEASUREMENTS	OVERALL ACCURACY
30 ± 4 ng/mL	10-100 ng/mL	94,40%

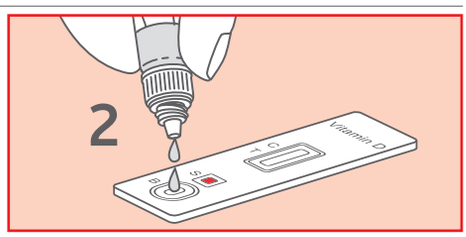
Performance data obtained by comparing the test with another EC marked Vitamin D Rapid Test.

CLINICAL EVIDENCES

1. Grant WB, Holick MF (June 2005). Benefits and requirements of vitamin D for optimal health: a review. Alternative Medicine Review.10 (2): 94–111.
2. Moyad MA. Vitamin D: a rapid review. DermatolNurs. 2009, 21:25-30
3. Holick MF (March 2006). "High prevalence of vitamin D inadequacy and implications for health". Mayo Clinic Proceedings. 81 (3): 353–73.

HOW TO USE IT





CONTENT: 20 test cassettes; 20 pipettes; 20 vials with diluent; 1 color card; 1 instructions for use leaflet.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
100066IP-20P	VITAMIN D RAPID TEST	20 TESTS	24 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

IRON FER RAPID TEST

Rapid immuno-chromatographic test for the detection of ferritin in whole blood or serum samples

5 min.

20 tests

POSITIVE

NEGATIVE

IRON STORAGE & FERRITIN

Ferritin is a protein whose role is to store iron in the body, essential element for oxygen transportation, cells multiplication and tissues and organs structure building. The level of ferritin is an excellent indicator of the amount of iron available to the body. Low levels of this protein in the blood are an indication of depleted iron stores, a condition that precedes the development of anaemia. Anemia affects 27% of the world's population: iron-deficiency anemia is the dominant cause (≥ 60%).

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present the following symptoms: unexplained fatigue, chronic headaches, leg pains, shortness of breath and persons suffering from gastrointestinal disorders such as Celiac disease and Helycobacter pylori infection. Who eat a purely vegetarian diet is also more likely to have iron deficiency. The test is also useful for everyone who takes integrators and wishes to monitor iron levels.

TEST PRINCIPLE

IRON FER RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of ferritin in whole blood, thanks to special gold conjugate antibodies embedded to a test strip.

TECH SPECS

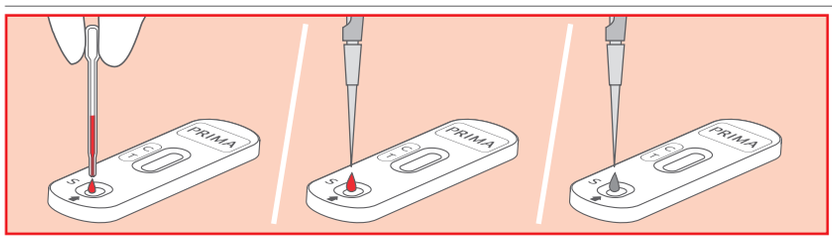
CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
30 ng/mL	100,00%	100,00%	100,00%

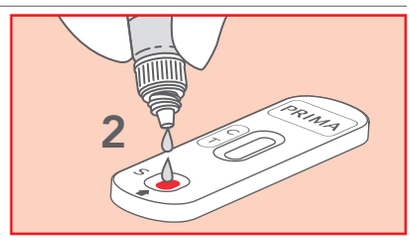
Performance data obtained by clinical study with 120 participants enrolled. Biokit Quantex Ferritin has been utilized as reference method.

CLINICAL EVIDENCES

1. Wick M, Pingerra W, Lehmann P, Iron metabolism: diagnosis and therapy of anemias, 5th ed, Vienna, New York: Springer Verlag, 2003; p. 151.
2. Worwood M. The laboratory assessment of iron status – an update. Clin Chim Acta 1997; 259: 3-23.
3. Kaltwasser JP, Werner E. Diagnosis and clinical evaluation of iron overload. Baillieres Clin Haematol 1989; 2; 363-89.
4. Baynes RD, Cook JD. Current issues in iron deficiency. Curr Opin Hematol 1996; 3:145-9.
5. Lee MH, Means RT Jr. Extremely elevated serum ferritin levels in a university hospital: associated diseases and clinical significance. Am J Med 1996; 98: 566-71.

HOW TO USE IT





CONTENT: 20 test cassettes; 20 pipettes; 1 vial with diluent; 1 instructions for use leaflet.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800025IP-20P	IRON FER RAPID TEST	20 TESTS	30 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

BOWEL FOB RAPID TEST

Rapid immunochromatographic test for the detection of fecal occult blood in stool samples

5 min.

20 tests

FOB (FAECAL OCCULT BLOOD)

Faecal Occult Blood (FOB) is the presence in the faeces of blood which is not clearly visible to the naked eye. FOB may be the consequence of gastrointestinal disorders, such as ulcers, polyps, colitis, diverticulitis, rhagades, haemorrhoids or even colorectal cancer (CRC). CRC is the second most frequent malignant disease in Europe: more than 400.000 people are diagnosed with this condition every year.
The signs of these lesions and disorders are often silent in the first phases, then searching for occult blood in the stool is an important early screening test.

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present symptoms related to gastrointestinal disorders.
The test is also recommended as check-up screening test from 45 years of age.

TEST PRINCIPLE

BOWEL FOB RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of the smallest amounts of blood in faeces samples, thanks to special gold conjugate antibodies embedded to a test strip.

TECH SPECS

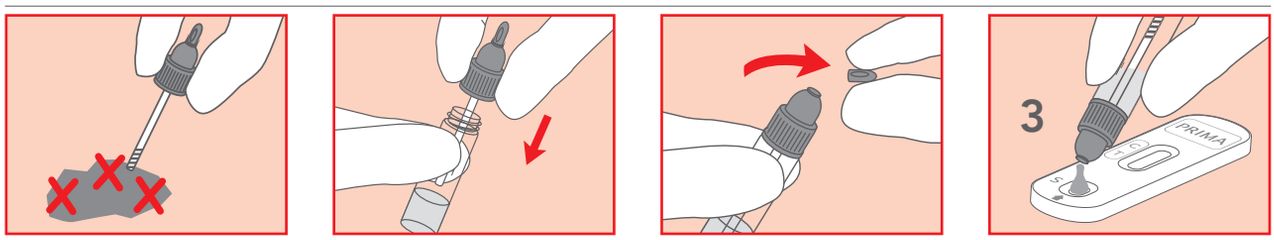
CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
40 ng/mL	78,70%	99,00%	92,60%

Performance data obtained by clinical study with 148 participants enrolled. Hb Fecale - Mascia Brunelli kit has been utilized as reference method.

CLINICAL EVIDENCES

1. Van Rossum Leo G. et al.: "Random Comparison of Guaiac and Immunochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population" Gastroenterology, Volume 135, Issue 1, 82 – 90.
2. Faivre J., Dancourt V., Denis B., Dorval E., Piette C., Perrin P., Bidan J.M., Jard C., Jung S., Levillain R., Viguier J., Bretagne J.F.: "Comparison between a guaiac and three immunochemical faecal occult blood tests in screening for colorectal cancer". European Journal of Cancer. 2012; 48(16):2969-76.
3. Benton S.C., Seaman H.E., Halloran S.P.: "Faecal Occult Blood Testing for Colorectal Cancer Screening: the past or the Future". Current Gastroenterology Reports. 2015; 17(2):428
4. European Commission. European guidelines for quality assurance in colorectal cancer screening and diagnosis. First edition 2010

HOW TO USE IT



CONTENT: 20 test cassettes; 20 vials with collection stick and diluent; 1 instructions for use leaflet.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800040IP-20P	BOWEL FOB RAPID TEST	20 TESTS	30 MONTHS

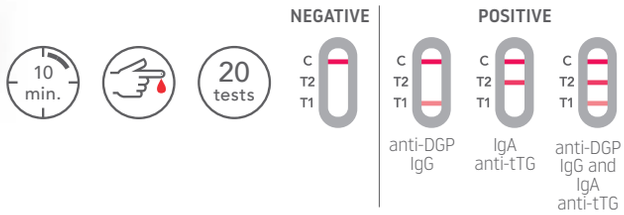
FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

CELIAC RAPID TEST

Rapid test for the qualitative detection of IgG anti-gliadin deamidated peptide (DGP) and IgA anti-tissue transglutaminase (tTG) antibodies in whole blood, serum or plasma samples for screening of celiac disease



CELIAC DISEASE

Celiac disease is an autoimmune disorder that affects genetically predisposed individuals and is caused by intolerance to gluten (a protein complex typical of certain cereals, especially wheat and corn) that leads to a state of chronic inflammation of the small intestine. Worldwide incidence is estimated to be 1.5% of population, with high incidence in women and children.
Recent studies shown that celiac subjects produce specific antibodies versus gliadin deamidated pepdide (IgG anti-DGP) and tissueTransglutaminase (IgA anti-tTG).

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present the following symptoms: weight loss, persistent diarrhea, bloating and stomach pain, constipation and tiredness. Significant growth delay can also be observed in children due to malabsorption of necessary nutrients.

TEST PRINCIPLE

CELIAC RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of IgG anti-gliadin deamidated peptide (DGP) and IgA anti-tissue transglutaminase (tTG) antibodies in whole blood or serum/plasma, thanks to special gold conjugate antibodies embedded to a test strip with two different test lines.

TECH SPECS

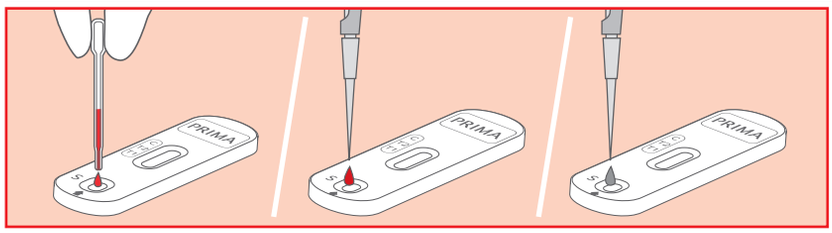
	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
T1 (IgG anti-DGP)	84,30%	90,10%	86,94%
T2 (IgA anti-tTG)	98,31%	98,02%	98,17%

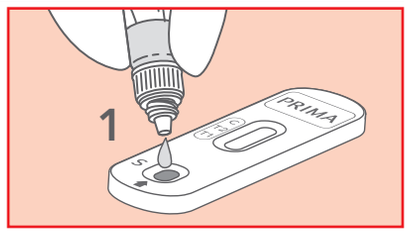
Performance data obtained on a total of 266 participants comparing the test with a quantitative commercial laboratory test used as a reference method (Thermo Fisher Phadia 250 - Thermo Fisher Scientific Inc.).

CLINICAL EVIDENCES

1. King, et al. 2020. Incidence of Celiac Disease Is Increasing Over Time: A Systematic Review and Meta-Analysis. The American Journal of Gastroenterology 115 (4): 507–25.
2. Lindfors, et al. Celiac disease. Nat Rev Dis Primers 5, 3 (2019).
3. Husby, Steffen, Sibylle Koletzko, Ilma Korponay-Szabó, Kalle Kurppa, Maria Luisa Mearin, Carmen Ribes-Koninckx, Raanan Shamir, et al. 2020. "European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Celiac Disease 2020". Journal of Pediatric Gastroenterology and Nutrition 70 (1): 141–56.
4. Al-Toma, et al. European Society for the Study of Celiac Disease (ESsCD) guideline for Celiac disease and other gluten-related disorders. United European Gastroenterol J. 2019 Jun;7(5):583-613.

HOW TO USE IT





CONTENT: 20 test cassettes; 20 pipettes; 1 vial with diluent; 1 instructions for use leaflet.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800077IP-20P	CELIAC RAPID TEST	20 TESTS	24 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

IVD CE

PRIMA PROFESSIONAL

HELICOBACTER PYLORI ANTIGEN RAPID TEST

Rapid immunochromatographic test for the qualitative detection of Helicobacter pylori Antigen in stool samples

10 min.

20 tests

HELICOBACTER PYLORI

Helicobacter pylori is a bacterium whose ideal habitat is the human gastric mucosa. The infection is estimated to affect 2/3 of the world's population and it is often asymptomatic, but it can sometimes cause gastritis and ulcers in the stomach or in the duodenum segment of the small intestine. Ulcers can sometimes bleed, causing anemia over long periods of time.
In the long term, infected people are 3 to 6 times more likely to develop stomach cancer.

WHO ARE THE INTENDED USERS

Healthcare professionals with patients who present the following symptoms: heartburn or pain in the upper part of the abdomen, especially in fasting or in the early morning - when the stomach is empty - nausea, reflux, loss of appetite, burping, weight loss and diarrhea.
The test is also indicated to those healthcare professionals who frequently get in touch with potential infected faeces samples to monitor thirself.

TEST PRINCIPLE

HELICOBACTER PYLORI ANTIGEN RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of *Helicobacter pylori* antigens in human faeces, thanks to special gold conjugate antibodies embedded to a test strip.

TECH SPECS

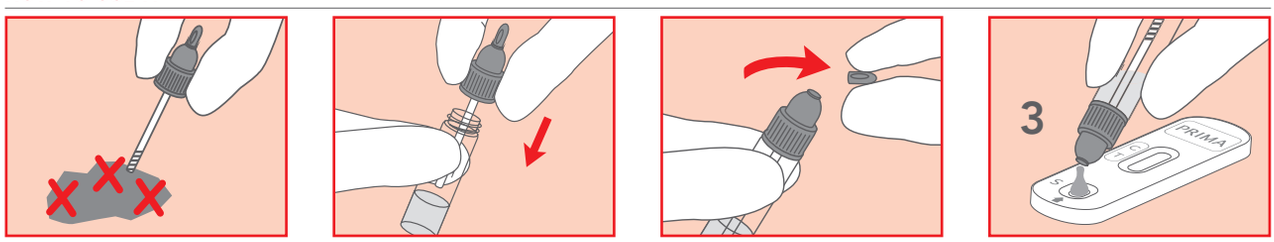
CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 ng/mL	95,20%	96,60%	96,00%

Performance data obtained by clinical study with 100 participants enrolled. ImmunoCard STAT!® HpSA® has been utilized as reference method.

CLINICAL EVIDENCES

1. Shimoyama T. "Stool antigen tests for the management of Helicobacter pylori infection." World Journal of Gastroenterology. 2013;19(45):8188-91.
2. Ana Isabel Lopes, Filipa F Vale, Mónica Oleastro. "Helicobacter pylori infection - recent developments in diagnosis." World Journal of Gastroenterology. 2014 July 28; 20(28): 9299-9313.
3. Andreas Mentis, Philippe Lehours, and Francis Francis Megraud. "Epidemiology and Diagnosis of Helicobacter pylori infection". Helicobacter. 2015 Sep;20 Suppl 1:1-7.
4. Zagari RM, Rabitti S, Eusebi LH, Bazzoli F. "Treatment of Helicobacter pylori infection: A clinical practice update." Eur J Clin Invest. 2018 Jan;48(1). doi: 10.1111/eci.12857

HOW TO USE IT



CONTENT: 20 test cassettes; 20 vials with collection stick and diluent; 1 instructions for use leaflet.

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800016IP-20P	HELICOBACTER PYLORI ANTIGEN RAPID TEST	20 TESTS	30 MONTHS

FOR PROFESSIONAL
IN-VITRO DIAGNOSTIC USE ONLY

KI SCREENING TEST
Canine NGAL Detection

The first and only rapid test for semi-quantitative detection of NGAL in urine for early screening of kidney damage in dogs

TEST PRINCIPLE

KI SCREENING TEST is a lateral flow immunochromatographic device, for veterinary use, for semi-quantitative detection of NGAL in dog urine samples.

WHO ARE THE INTENDED USERS

The device is intended to be used by healthcare professionals in order to quickly determine the concentration of NGAL in dog urine, which is directly proportional to the severity of kidney damage and indicative of potential clinical settings.

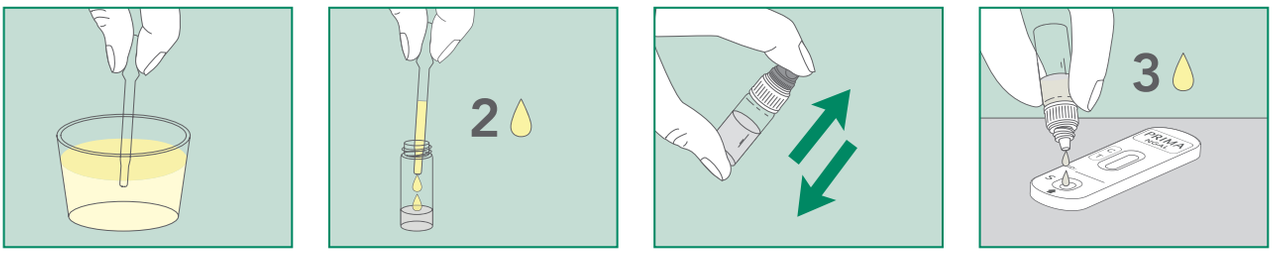
ANALYTICAL PERFORMANCES

SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
99,21%	98,15%	98,90%

CLINICAL EVIDENCES

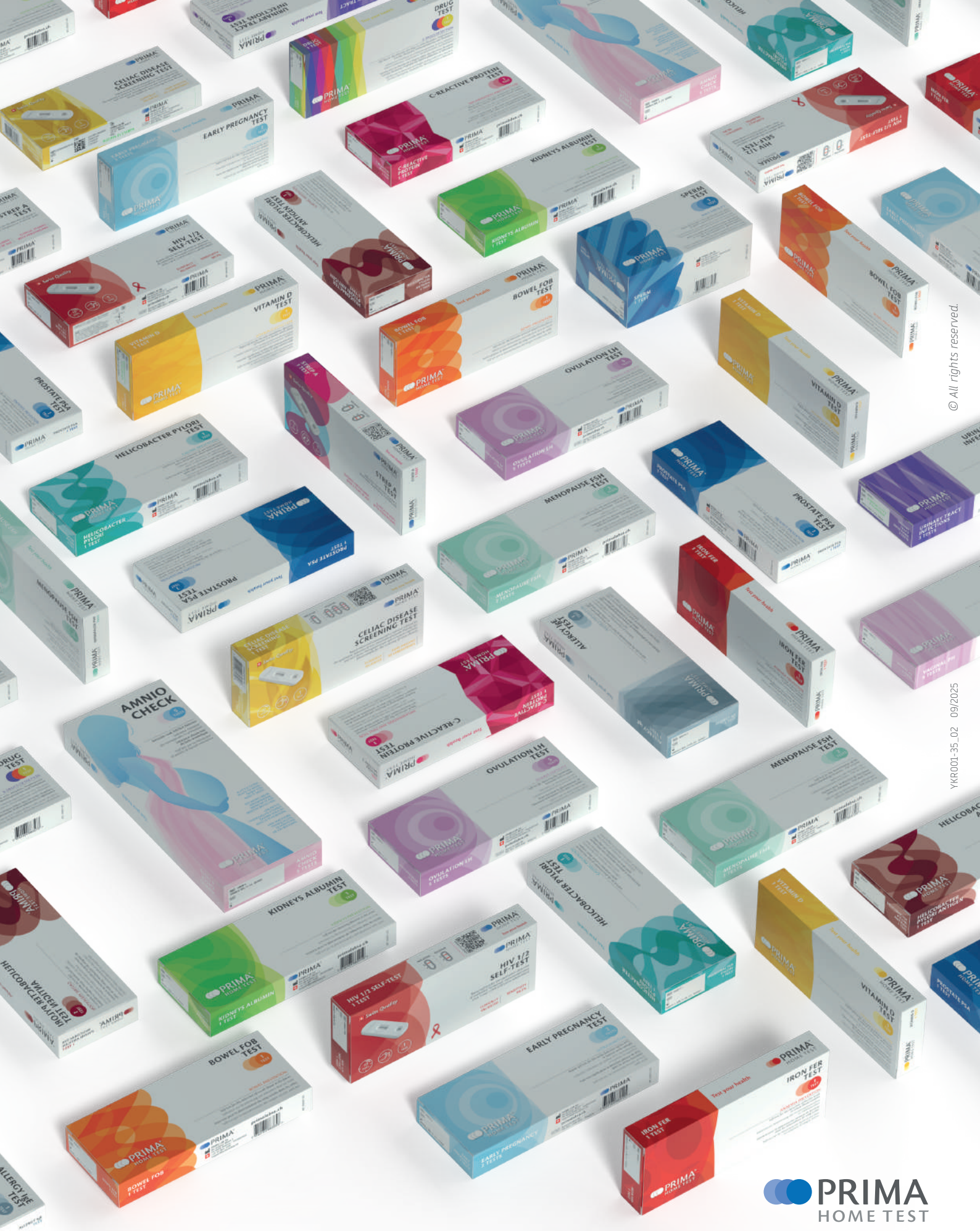
1. F. Tagliasacchi, Abstract: Urinary neutrophil gelatinase-associated lipocalin (NGAL): A rapid lateral flow test in canine practice. Oral communication at the 33rd ECVIM-CA Congress, 2023, Barcellona.
2. Davis J, Raisis AL, Miller DW, Hosgood GL, Rossi G. Analytical validation and reference intervals for a commercial multiplex assay to measure five novel biomarkers for acute kidney injury in canine urine. Res Vet Sci. 2021 Oct;139:78-86.
3. Lee YJ, Hu YY, Lin YS, Chang CT, Lin FY, Wong ML, Kuo-Hsuan H, Hsu WL. Urine neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for acute canine kidney injury. BMC Vet Res. 2012 Dec 28;8:248.
4. Nabity M, Hokamp J. Urinary Biomarkers of Kidney Disease in Dogs and Cats. Vet Clin North Am Small Anim Pract. 2023 Jan;53(1):53-71. doi: 10.1016/j.cvsm.2022.07.006. Epub 2022 Oct 19. PMID: 36270837.
5. Steinbach S, Weis J, Schweighauser A, Francey T, Neiger R. Plasma and urine neutrophil gelatinase-associated lipocalin (NGAL) in dogs with acute kidney injury or chronic kidney disease. J Vet Intern Med. 2014 Mar-Apr;28(2):264-9. doi: 10.1111/jvim.12282.

HOW TO USE IT



CONTENT: Test cassettes; single-use pre-dosed bottles; colour chart; pipettes; instructions for use leaflet;

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800087-5	KI SCREENING TEST	5 TESTS	18 MONTHS



YKR001-35_02 09/2025

PRIMA

PRIMA Lab SA Via Antonio Monti 7 CH-6828 Balerna Switzerland
T. +41(0)91 605 1030 **primalabsa.ch**

PRIMA HOME TEST

PRIMA PROFESSIONAL

PRIMA VETERINARY