







1996 BEGINNING

- Hundred and fifty square meter workshop in Izmir
- First and only Turkish manufacturer specialized in Rapid Tests
- Only one product in the line: Pregnancy tests
- Ten percent share of the domestic market in the first twelve months

2000 INTERNATIONAL EXPANSION

- First to receive CE approval for home-use pregnancy tests
- First international client: A German chain pharmacy with twelve thousand branches

2003 FORMATION OF SK RESEARCH AND DEVELOPMENT COMPANY

- A new and separate company within the structure of Turklab
- Dedicated to Science
- New investments and research for increasing range & variety of products

2008 PRODUCT LINE EXTENSION

- Relocation to a bigger and better facility
- Increased production: Availability of new and diverse products
- First to achieve CE approval for Anti-HIV, Anti-HCV, HBsAg and Anti-HBs Tests
- Increased export sales : Thirty four countries

2010 CORPORATE GROWTH

- Acquisition of Gökhan Laboratories: one of the first laboratory equipment producers in Turkey
- Product line extension: a sharp increase in the variety & production

2014 WIND OF CHANGE

- Final relocation to ITOB Organized Industrial Zone, current facility equipped with higher technology
- Institutionalization of the family business
- Enhancement of the company image
- Enhancement of the overall performances of production systems
- Increased export sales:seventy countries
- Domestic market leader: seventy percent share of the domestic market

2022 NEW CHAPTER

- Our capacity has reached four factories over the years.
- Test-IT GmbH has been established in Germany.
- Our production became completely automated.
- First antigen and antibody production have been launched with raw material production.
- Food test kits design has been started.
- Moves forward as global leader with its own test kits produced in the 10.000m² indoor facility with the latest technology.

ABOUT

• TURKLAB MEDICAL DEVICES INC. founded by Dr.Şahin YAĞLIDERE in 1996, İzmir, became one of the most important companies that lead the IVD sector in the world thanks to its infrastructure, technology, quality, continuous investment, and last but not least ambition for growth.

RESEARCH & DEVELOPMENT

- TURKLAB has experienced a steady growth since it was founded in 1996.
- R&D studies has been actively conducted in addition to manufacturing practices.
- Accordingly, TURKLAB is in close collaboration with the scientific community and has been conducting international research which leads the field.
- To name a few, **TURKLAB** has ongoing projects in cooperations with several universities in Turkey and abroad, the Ministry of Industry and Technology, as well as the Scientific and Technological Research Council of Turkey (TUBITAK).

QUALITY

- The first company to receive CE for the Pregnancy (hCG) Test
- The first company to obtain and still hold the CE certificate for HIV, HCV, HBsAg and Anti-HBs tests.
- FDA approval in OTC (hCG) tests
- FDA approval for personal hCG, LH, FSH tests
- BfArM (Germany) Approval for Covid-19 Ag Professional Testing and Home Testing
- Compliance with Good Manufacturing Practices (GMP)
- ISO 9001
- ISO 13485
- Approved by the Turkish Ministry of Health
- Our tests are registered in the Ministries of Health of many countries in Europe, Asia, Africa, the Middle East, and North America.
- HSC Approval in Covid-19 Ag Professional Tests



PRODUCTION

Every single decision Turklab takes is driven by the initiative of developing, producing, packaging in a way that goes beyond basic compliance standards.





Thus, Turklab has developed its production systems tailor-made for the production of in vitro diagnostic devices; its production line is one of the most advanced solutions available in the field today.

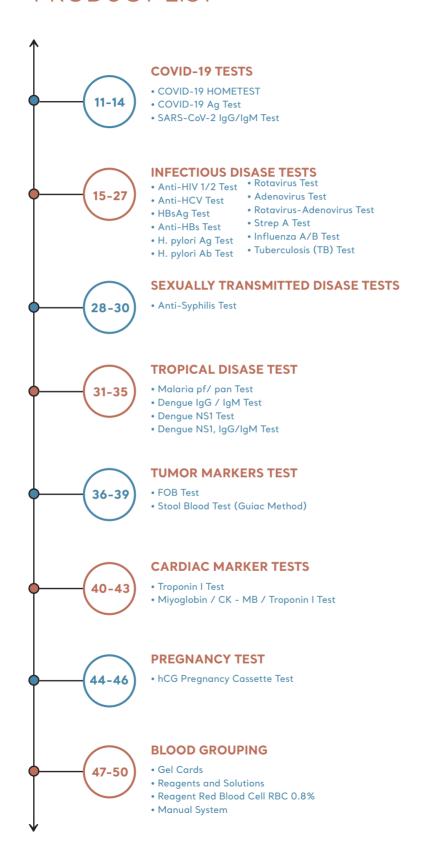
PRODUCTS

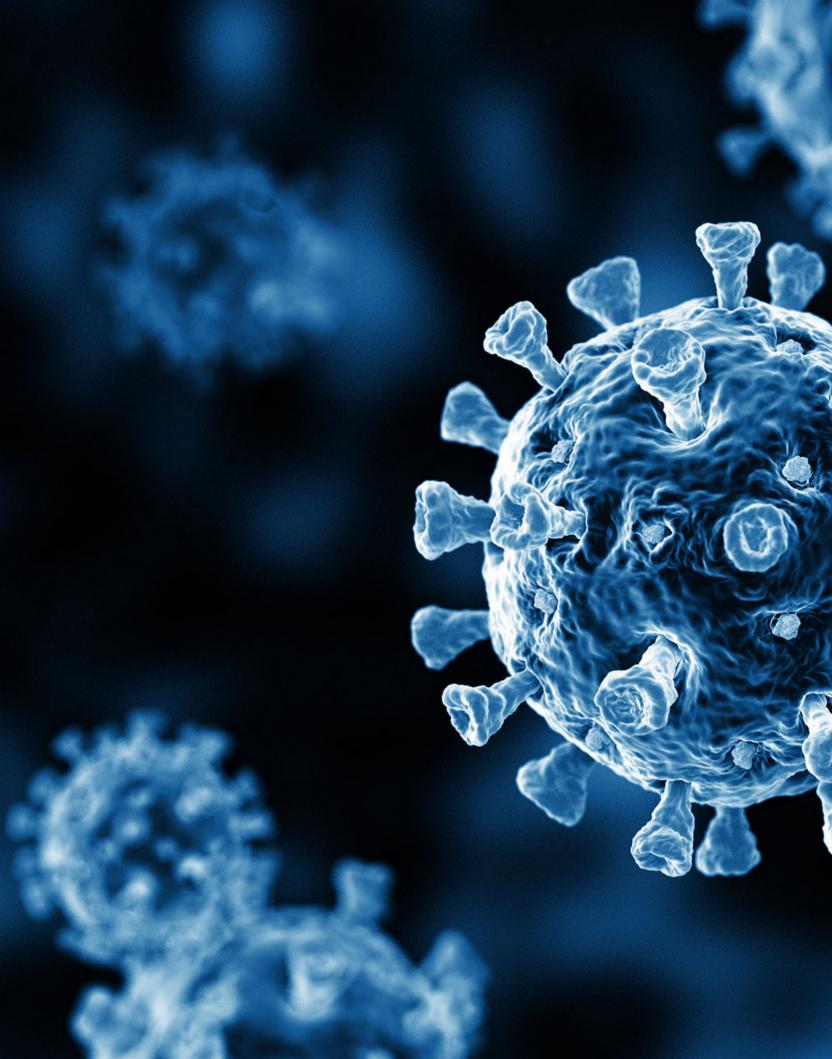
Turklab continues to expand with innovative ideas to provide "Quality Products for Today and the Future".

Fast and easy access, up-to-date technology and worldwide presence are considered to be the main reasons for the professional end-users, who value the unique quality and service, to create long term relationships with the company.



PRODUCT LIST





COVID-19 TESTS

COVID-19 (Coronavirus disease 2019) is an acute and infectious respiratory disease caused by the SARS-CoV-2 virus, a single stranded RNA virus from the *Coronaviruses* family.

SARS-CoV-2 emerged in 2019 and has been classified as a global pandemic since March 2020.

Symptoms can range from little or no symptoms to severe illness or death.

The virus can spread from an infected person's mouth or nose in small liquid particles when they cough, sneeze, speak, sing or breathe. These particles range from larger respiratory droplets to smaller aerosols.



COVID-19 Ag HOME TEST

C €₁₄₃₄

INTENDED USE

Turklab's COVID-19 Ag Home Test is a rapid immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasal swabs for self testing.

- No need for trained professionals or special equipment to perform the test.
- Varified detection of Omicron variant's nucleocapsid antigen.
- Showed no reactivity with other human coronavirus species or other respiratory viruses.
- All the components of the test are included in the kit.

PERFORMANCE EVALUATION

Sensitivity: 96,58%Specificity: 99,47%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
COVID-19 Ag HOME TEST	CASSETTE	NASAL SWAB	20 Min.	1 or 5	Test Cassette + Sterile Swab + Sample Extraction Reagent Tube+ Instructions For Use



COVID-19 Ag TEST

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INTENDED USE

Turklab's COVID-19 Ag Test is a rapid immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in human nasal swabs in a professional environment.

- Realiable results in the acute phase (first 5-7 days) of COVID-19 infection.
- Varified detection of Omicron variant's nucleocapsid antiaen.
- Showed no reactivity with other human coronavirus species or other respiratory viruses.

PERFORMANCE EVALUATION

Sensitivity: 96,58%Specificity: 99,47%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
COVID-19 Ag	CASSETTE	NASAL SWAB	20 Min.	25	Test Cassette + Sterile Swab + Sample Extraction Reagent Tube + Instructions For Use





SARS-CoV-2 IgM/IgG Ab TEST

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COVID-19 infection eicits an immune response in the human body which includes the emergence of antibodies spesific to SARS-CoV-2 antibodies. The antibody response to COVID-19 can take days to weeks to develop and varries considerably among individuals.

INTENDED USE

Turklab's SARS-CoV-2 IgM/IgG Ab Test is a rapid immuno-chromatographic assay for the qualitative detection of antibodies (IgG and IgM) generated against SARS-CoV-2 nucleocapsid antigen in human serum, plasma or whole blood.

- Detects both IgG and IgM isotypes.
- Wide range of samples can be used, plasma, serum, capillary blood, or venous blood.
- Showed no cross reactivity with antibodies to other human coronavirus species, other respiratory viruses, or common disases.

PERFORMANCE EVALUATION

SARS-CoV-2 laM

SARS-CoV-2 lqG

Positive coincidence rate: 87,54%
Negative coincidence rate: 98,43%
Total coincidence rate: 93,33%

Positive coincidence rate: 92,88%
Negative coincidence rate: 99,06%
Total coincidence rate: 96,17%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
SARS- CoV-2 IgM/IgG Ab	CASSETTE	WB/S/P	15 Min.	40	Test Cassette + Pipette + Dilluent + Instructions For Use

INFECTIOUS DISEASES TESTS

Infectious diseases are worldwide common illnesses caused by the entry of harmful agents, such as viruses, bacteria, fungi, and parasites, into the body. Some infectious diseases are contagious (or communicable), that is, spread from one person to another while other infectious diseases can be seen due to the spread by germs carried through the air, water, food, soil, or by vectors (like biting insects) or by animals.

The most common infectious diseases caused by viruses are the flu (influenza), hepatitis, and HIV. Early detection of infectious diseases and rapid and accurate identification of the underlying agent plays a crucial role in all prevention and treatment strategies.



Anti-HIV 1/2 TEST

C €₁₄₃₄

HIV (Human Immunodeficiency Virus) is a single-stranded, enveloped RNA virus that attacks the body's immune system, especially the CD4+ white blood cells (CD4 expressing T lymphocytes). Despite the homology in conserved regions, there are two main types of human immunodeficiency virus: HIV-1 and HIV-2. HIV-1 virus is divided into four groups: M, N, O, and P. The most widespread group, M, is also classified into nine subtypes; A, B, C, D, F, G, H, J, and K.

It is not possible to cure the disease once a person is infected. However, with the current medical therapies, controlling the infection and preventing the progression of the disease is possible.

For most infected people, flu-like symptoms last for a few days longer. However, due to a high number of asymptomatic patients, the only way to ensure having an HIV infection is to get tested.

INTENDED USE

Turklab's Anti-HIV 1/2 Test is a rapid, immunochromatographic assay for the qualitative detection of antibodies generated against all subtypes of HIV-1 and HIV-2 (Type 2) in human serum, plasma, and whole blood samples.

• Able to detect all HIV-1 (Type1) groups, including Group O.

PERFORMANCE EVALUATION

Sensitivity: 100%Specificity: 100%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
Anti -HIV 1/2	CASSETTE	WB/S/P	15 Min.	40	Test Cassette + Pipette + Dilluent + Instructions For Use



Anti-HCV TEST

C €₁₄₃₄

Hepatitis C is a liver infection caused by the Hepatitis C virus, a single-stranded, enveloped RNA virus.

The severity of Hepatitis C disease ranges from an acute, short-term, mild illness to chronic, lifelong disease. Chronic Hepatitis C, seen by most people infected with HCV, may cause serious life-threatening illnesses like liver cancer and cirrhosis. The current treatments can cure most people in the early period of hepatitis C disease.

Early diagnosis of hepatitis C virus (HCV) infection is crucial to prevent further transmission in high-risk groups.

Hepatitis C disease is a worldwide disease that occurs in all WHO regions. The most affected regions with a high number of chronic infection cases are Eastern Mediterranean Region, European Region, South-East Asia, and Western Pacific Region.

Seven HCV genotypes and more than 60 subtypes have been identified globally. Genotypes 1, 2, and 3 are the most common, accounting for about 60% of global infections.

INTENDED USE

Turklab's Anti-HCV Test is a rapid, immunochromatographic assay for the qualitative detection of antibodies generated against proteins that are encoded by conserved sequences of HCV genome in human serum, plasma, and whole blood samples.

• Detects antibodies generated against the proteins encoded by all HCV genotypes'; most conserved parts of Core, NS3, NS4, and NS5 regions in the HCV genome.

PERFORMANCE EVALUATION

Sensitivity: 100%Specificity: 100%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
Anti -HCV	CASSETTE	WB/S/P	15 Min.	40	Test Cassette + Pipette + Dilluent + Instructions For Use





HBsAg TEST

Hepatitis B is a liver infection caused by the Hepatitis B virus, a partially double-stranded DNA virus.

The severity of Hepatitis B disease ranges from an acute, short-term illness to a chronic, lifelong disease that puts people at high risk of death from cirrhosis, liver failure, and liver cancer. Treatment against chronic hepatitis B is possible with medications, while there is no cure for acute infections.

The virus is transmitted through contact with an infected person's blood and other bodily fluids. The presence of hepatitis B surface antigen (HBsAg) indicates that the person is contagious.



INTENDED USE

Turklab's HbsAg Test is a rapid, immunochromatographic assay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human serum, plasma, and whole blood samples.

- The presence of HBsAg indicates that the person is infected
- Direct detection of virus antigens and all subtypes of HBsAg so accuracy is high.

PERFORMANCE EVALUATION

Sensitivity: 100%Specificity: 99,89 %





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
HBsAg	CASSETTE	WB/S/P	15 Min.	40	Test cassette + Pipette + Diluent Instructions For Use



Anti-HBs TEST

C €₁₄₃₄

Hepatitis B is accepted as a significant global health problem seen globally, where the effects of the disease are seen as highest in the Western Pacific Region, the African Region, and the Eastern Mediterranean Region.

Prevention of hepatitis B is possible with a safe and effective vaccine that provides 98% to 100% protection. Less than 5% of people who become infected with hepatitis B in adulthood will develop chronic hepatitis. In contrast, approximately 95% of people who become infected during infancy or early childhood will develop chronic hepatitis, which shows the importance of infant and child immunization.

The presence of anti-HBs is generally interpreted as a marker for immunity to hepatitis B after recovery from the HBV infection. Also, successfully vaccinated individuals develop antibodies against Hepatitis B (Anti-HBs).

INTENDED USE

Turklab's Anti-HBs Test is a rapid, immunochromatographic assay for the qualitative detection of antibodies against Hepatitis B virus surface antigen (HBsAg) in human serum, plasma, and whole blood samples.

- The presence of anti-HBs is generally considered for recovery and immunity from HBV infection.
- Anti-HBs positivity also means that the patient might have been vaccinated.

PERFORMANCE EVALUATION

Sensitivity: 100%Specificity: 100%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
Anti-HBs	CASSETTE	WB/S/P	15 Min.	40	Test cassette + Pipette + Diluent + Instruc- tions For Use





H.pylori Ag TEST

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Helicobacter pylori (H.pylori) is a small, gram-negative, spiral-shaped bacterium that infects the stomach and duodenum and causes for gastrointestinal diseases. H.pylori is found to be the major cause of acute and chronic gastritis, peptic ulcer disease, gastric carcinoma, and lymphoma. Although it is a disease seen all over the world, its prevalence is more common in developing countries. The transmission of H.pylori infection can occur by fecal-oral and oral-oral routes and also contaminated water.

Despite the gnawing and burning epigastric pain, *H.pylori* infection is commonly asymptomatic. Since then, early diagnosis of the infection plays a crucial role and enables to the prevention of further serious complications by treatment.

For the diagnosis, both invasive and noninvasive methods are used. By HpSA (*H.pylori* Stool Antigen) testing, it is possible to diagnose the infection and also monitor the treatment efficiency against the *H.pylori*.

INTENDED USE

Turklab's *H.pylori* Ag Test is a rapid, immunochromatographic assay for the qualitative detection of *H.pylori* antigens in human feces samples to diagnose the *H.pylori* infection.

• Clean and reliable use, ease of use with the sample collection tube prefilled with diluent.

PERFORMANCE EVALUATION

Sensitivity :99,9%Specificity :99,9 %





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
H.Pylori Ag	CASSETTE	FECES	10 Min.	40	Test cassette + Pipette + Sample Collection Tube with Dilution Buffer + Instructions For Use





H.pylori Ab TEST

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Infection with the gram-negative *Helicobacter pylori* bacteria elicits an immune response in the human body including the production of specific anti- *H.pylori* antibodies in blood and other body fluids.

The antibodies aid the body in the fight against the infection and can be used for the detcection of past and possibly active *H.pylori* infections.

INTENDED USE

Turklab's *H.pylori* Ab Test is a rapid, immunochromatographic assay for the qualitative detection of the antibodies against the *H.pylori* antigens in human whole blood, serum or plasma.

• If antibodies are present, it may mean that they are there to fight *H. pylori* bacteria.

PERFORMANCE EVALUATION

Sensitivity:98,7%

• Specificity:93,2 %



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
H.Pylori Ab	CASSETTE	WB/S/P	10 Min.	40	Test cassette + Pipette + Dilution Buffer + Instructions For Use





Rotavirus TEST

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Rotaviruses, a genus in the family of Reoviridae, are double-stranded RNA viruses that are accepted as the major cause of gastroenteritis leading causing of severe, dehydrating diarrhea in young children and infants.

After 2-3 days of *Rotavirus* infection, mild to severe symptoms that include generally watery diarrhea, loss of appetite, and dehydration (loss of body fluids) can be seen.

Rotavirus infection can be transmitted primarily by the fecal-oral route, directly from an infected person to person, or indirectly via contaminated fomites.

Specific treatment against the *Rotavirus* has not been found yet but it is possible to reduce the symptoms and the mortality with proper medical treatment and early diagnosis.

INTENDED USE

Turklab's *Rotavirus* Test is a rapid, immunochromatographic assay for the qualitative detection of *Rotavirus* antigens in human feces samples.

- · Clean and reliable use.
- Ease of use with the sample collection tube with prefilled diluent.

PERFORMANCE EVALUATION

Sensitivity: 99,9%Specificity: 99,0%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
ROTAVIRUS	CASSETTE	FECES	10 Min.	40	Test cassette + Pipette + Sample Collection Tube with Dilution Buffer + Instructions For Use



Adenovirus TEST

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Adenoviruses, members of the family Adenoviridae, are non-enveloped double-stranded DNA viruses that cause mild to severe illness by mainly infecting the respiratory tract, eye, and gastrointestinal tract. Infections can occur at any age but the prevalence is more in young people, especially in children.

Flu-like symptoms including fever and sore throat, pneumonia, acute bronchitis, and acute gastroenteritis are commonly seen as symptoms of *Adenovirus* infection. People who already have cardiovascular or respiratory disease or those with weak immune systems are at higher risk of having more severe *Adenovirus* infection. *Adenovirus* infections are usually transmitted through close contact with an infected person or fecal-oral.

Adenoviruses are classified into 6 subgenera and more than 40 subtypes. Enteric Adenoviruses, particularly types 40 (Ad40) and 41, are the most common cause of diarrhea in children every term of the year after rotavirus infections. Early diagnosis of the infection with effortless tests, has a crucial role in starting a treatment that may relieve symp-

INTENDED USE

Turklab's *Adenovirus* Test is a rapid, immunochromatographic assay for the qualitative detection of *Adenovirus* antigens in human feces samples.

- · Clean and reliable use.
- Ease of use with the sample collection tube with prefilled diluent.

PERFORMANCE EVALUATION

Sensitivity: 99,9%Specificity: 99,3%









Rotavirus Adenovirus TEST

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Rotavirus and Adenovirus are two infectious agents that cause mild to severe diseases.

These viral pathogens have been isolated throughout the world where the infections are most frequently seen in children less than two years of age but have been found in patients of all ages. Rapid and accurate diagnosis of gastroenteritis due to *Adenovirus* and rotavirus helps establish the etiology of gastroenteritis and related patient management.

INTENDED USE

Turklab's *Rotavirus Adenovirus* Test is a rapid, immunochromatographic assay for the qualitative detection of *Rotavirus and Adenovirus* antigens in human feces samples.

- Clean and reliable use.
- Ease of use with the sample collection tube with prefilled diluent.

PERFORMANCE EVALUATION

Rotavirus:

Sensitivity :99,9%

• Specificity:98,4%

Adenovirus:

• Sensitivity:99,9%

• Specificity:99,0%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
ROTAVIRUS-ADENOVIRUS	CASSETTE	FECES	10 Min.	40	Test cassette + pipette + sample collection tube with extraction buffer + instructions for Use



Strep A TEST

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Bacteria called group A Streptococcus (group A strep) can cause many infections ranging from minor illnesses to severe and deadly diseases.

Streptococcal pharyngitis, strep throat, scarlet fever, and cellulitis are the common diseases caused by Group A Strep, which can be found in the throat and skin. Although not very common, SSTT (Streptococcal toxic shock syndrome) can be seen due to the spread of group A strep bacteria into the bloodstream and deep tissues.

INTENDED USE

Turklab's *Strep A* Test is a rapid, immunochromatographic assay for the qualitative detection of group *A Streptococcus* in throat swab samples to aid in diagnosing Group A Streptococcal infection.

- Positive and negative controls are included in the kit.
- A workstation and test tubes are also provided with the kit.

PERFORMANCE EVALUATION

Sensitivity:97,3%Specificity:99,0%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
STREP A	CASSETTE	THROAT SWAB	5 Min.	40	Test cassette+ pipette+test tube+sterile swab+reagent 1+ reagent 2+ work station+Strep A positive control+ Strep A negative control + instructions for use.





Influenza A/B TEST



Influenza (flu) is a contagious respiratory illness caused by Influenza viruses that infect the nose, throat, and lungs. Influenza viruse is negative-sense, single-stranded RNA (ssR-NA) viruse and divided into four different types.

Among the four subtypes of Influenza virus, Influenza A and B types are the both common causes of acute respiratory ilnesses.

Symptoms of Influenza are not specific and may include sudden cough, fever, weakness and sore throat which may last 2-3 weeks. Diagnostic tests available for detection of influenza viruses in respiratory specimens.

INTENDED USE

Turklab's Infuenza A/B Test is a rapid, immunochromatographic assay for the qualitative detection of Influenza A/B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens.

- Able to detect most common types of *Influenza* virus
- Differential detection of A and B types with 3 lines.

PERFORMANCE EVALUATION

Sensitivity: 99,10% Specificity: 98,68%

Influenza

Nasal Swab Specimen | Throat Swab Specimen

Sensitivity: 95,59%

Specificity: 99,42%

Nasal Aspirate Specimen

Sensitivity: 99,03% Specificity: 99,17%

Sensitivity: 97,56%

Specificity: 99,21%

Nasal Swab Specimen | Throat Swab Specimen

Sensitivity: 94,44% Specificity: 99,35% Nasal Aspirate Specimen

Sensitivity: 97,78% Specificity: 99,48%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
INFULENZA A/B	CASSETTE	NASAL/NASOPHARYNGEAL /THROAT SWAB, NASAL ASPIRATE.	15 Min.		Test cassette, steril swab, extraction test tube and extraction tube tips, extraction reagent, work station, influenza A and B positive control swab, influenza A and B negative control swab and instructions for use.



Tuberculosis (TB) TEST

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Tuberculosis (TB) is a gram-positive bacterial infection spread through inhaling tiny droplets from the talks, coughs, or sneezes of an infected person. Areas of poor ventilation pose the greatest risk of exposure to infection.

The bacteria *Mycobacterium tuberculosis*, which causes tuberculosis infection, mostly affects the lungs.

TB is considered a major global health problem and the heaviest effects of the disease are seen in South-East Asia (43%), then Africa (25%), and finally the Western Pacific (18%).

According to the latest data announced by the World Health Organization, approximately 10 million people globally are annually diagnosed with Tuberculosis and 1.5 million people die from TB each year.

TB continues to be the leading cause of morbidity and mortality globally and in many countries, and is preventable and treatable. Early diagnosis and treatment are very important at this point.

INTENDED USE

Turklab's *Tuberculosis* Test is a serological and rapid immunochromatographic assay for the qualitative detection of antibodies (Isotypes of IgG, IgM and IgA) generated against *Mycobacterium tuberculosis* antigens in whole blood, serum or plasma specimens.

- IgA, IgM and IgG are fully detected.
- · Isotypes of TB are fully detected.

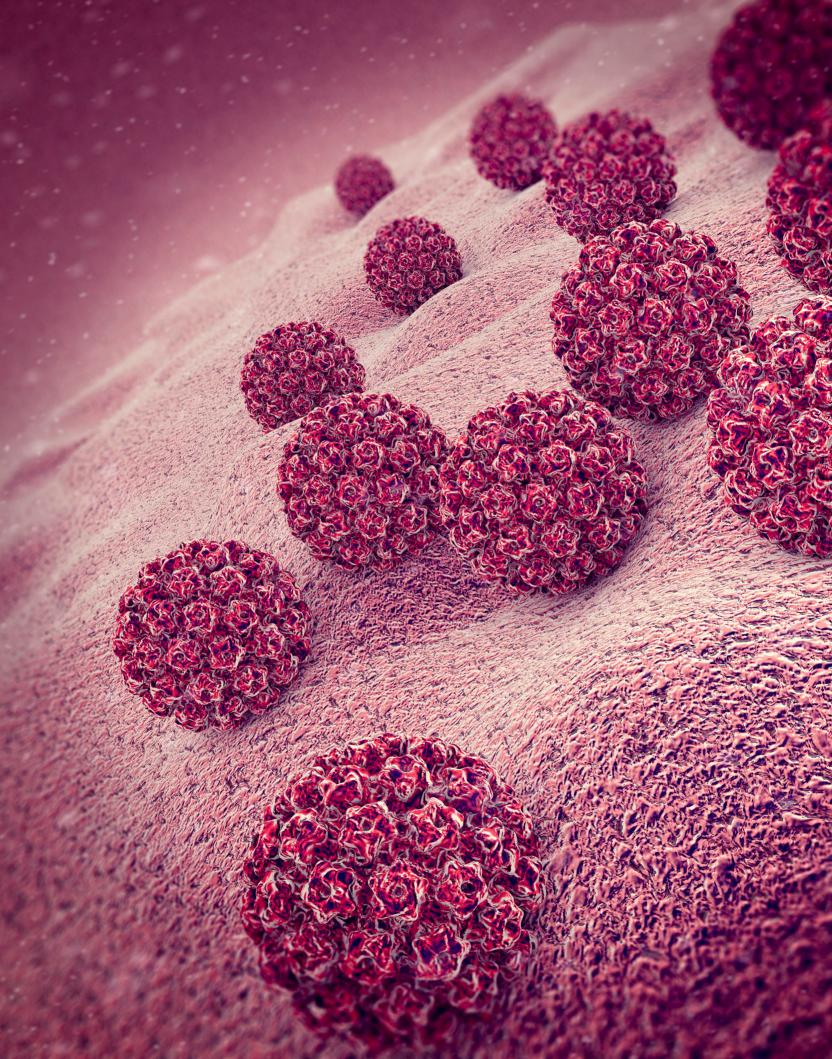
PERFORMANCE EVALUATION

Sensitivity: 85,0%Specificity: 99,0%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
TUBERCULOSIS (TB)	CASSETTE	WB/S/P	10 Min.	40	Test cassette+pipette + diluent + instructions for use.





SEXUALLY TRANSMITTED DISEASES TESTS

Sexually transmitted diseases (STDs), which can be caused by bacteria, viruses, or parasites, are infections transmitted from an infected person to an uninfected person through oral, anal, and vaginal sexual contact.

The most common STDs include syphilis, gonorrhea, and chlamydia. Untreated STDs can lead to devastating and sometimes long-term complications. Early and rapid diagnosis of STDs increases the chance to limit the effects of the disease since many STDs have no signs or symptoms. Due to their inter-relationships with HIV/AIDS, STDs are an important global health priority.



Anti-Syphilis Test

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Syphilis is a sexually transmitted infection (STI) caused by bacteria *Treponema pallidum* and it is curable. *Treponema pallidum* is a gram-negative and micro-aerophilic bacteria, which is a member of the *Spirochaetaceae* family. *Treponema* is mostly transmitted by direct contact with the active lesion. However, it may also be transmitted from mother to fetus during pregnancy or at birth and result in congenital syphilis.

As a result of the serological response in individuals exposed to syphilis infection, both non-specific and specific anti-*Tre-*ponema pallidum antibodies are produced.

Anti-treponemal IgM starts increasing and reaches detectable levels after syphilis lesions are observed as a result of a syphilis infection. Anti-treponemal IgG antibodies can be detected starting from the fourth week of infection. Therefore, it is possible to detect the anti-treponemal IgG and IgM antibodies in many patients after symptoms begin to appear.

INTENDED USE

Turklab's Anti-Syphilis Test is an immunochromatographic assay for the qualitative detection of treponemal antibodies (IgA, IgM, IgG) generated against *Treponema pallidum* antigens (17 kDa, 15 kDa, 47 kDa) in human whole blood/serum/plasma with high sensitivity and specificity.

PERFORMANCE EVALUATION

Sensitivity: 99,9%Specificity: 99,8%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
Anti-SYPHILIS	CASSETTE	WB/S/P	20 Min.	40	Test cassette + pipette + diluent + instructions for use.

■ TROPICAL DISEASES TESTS

Tropical diseases are infectious diseases that may be unique or more prevalent in tropical and subtropical regions. Tropical diseases such as dengue and malaria can be transmitted to a person through physical contact, airborne routes or can be spread via contaminated food and water sources. Some disease agents are spread by an intermediate carrier called 'vector' such as an insect.



Malaria TEST

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Malaria is a severe mosquito-borne disease caused by 5 species of parasites of the *Plasmodium* genus (*P. vivax*, *P. falciparum*, *P. malariae*, *P. ovale*, and *P. knowlesi*), *Plasmodium falciparum* infection is the one most associated with severe Malaria and can even lead to death. Malaria is characterized by high fevers, shaking chills, and flu-like illness. Early diagnosis is crucial for treatment and controlling the infection's spread in the community.

Malaria is treatable and curable if diagnosed quickly and treated appropriately, and delay in diagnosis and treatment is a leading cause of death in malaria patients

The five *Plasmodium* species share a 'Pan-*Plasmodium*' enzyme called aldolase that is commonly investigated to confirm a malaria infection in lateral flow immunoassays. In the case of *P.falciparum*, the histidine-rich protein II (HRP-II) is widely present in *P.falciparum* infections and can be also detected in the blood during the infection.

INTENDED USE

Turklab's Malaria Test is a rapid chromatographic immunoassay for the qualitative detection of Malaria as well as distinguishing the causing parasite species by detecting pan-*Plasmoduim* aldolase antigen and *P.falciparum* spesific HRP-II antigen in whole blood.

- Verified no cross reactivity with with HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, HCV, H. Pylori, MONO, CMV, Rubella and TOXO positive controls.
- Wide range of samples can be used, plasma, serum, capillary blood, or venous blood.
- Only a small volume of sample (5 μl) is needed.

PERFORMANCE EVALUATION

For Pan: For P.f:

Sensitivity: 99,9%Specificity: 99,9%Specificity: 99,1%









Dengue IgG/IgM TEST

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Dengue is a tropical disease caused by the mosquito-borne dengue virus (DENV), a single-stranded RNA virus of the Flaviviridae family.

The virus spreads between people through bites of Aedes aegypti and Aedes albopictus mosquito species.

About half of the world's population lives in Dengue's risk areas (tropical and subtropical climates) and Dengue is considered a primary illness in those areas.

Dengue infection elicits an immune response in the human body, including the emergence of IgM and IgG antibodies against the virus that can be detected in the blood. Primary infection of Dengue is characterized by elevated levels of IgM antibodies, while high levels of IgG antibodies accompany the secondary infection.

INTENDED USE

Turklab's Dengue IgG/IgM Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) generated against *Dengue* virus in human whole blood/serum/plasma as an aid in the diagnosis of primary and secondary Dengue infections.

- Detects both IgG and IgM isotypes (types).
- A wide range of samples can be used, including plasma, serum, capillary blood, or venous blood.
- A small sample volume (5-10 μl) is needed.

PERFORMANCE EVALUATION

Sensitivity: 95,8%Specificity: 99,9%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
DENGUE IgG/IgM	CASSETTE	WB/S/P	10 Min.	40	Test cassette + diluent + instructions for use.





Dengue NS1 TEST

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The non-structural protein NS1 of the dengue virus is secreted into the bloodstream during the acute stage of Dengue infection (0-7 days).

As there is no specific treatment for Dengue, early detection is critical as it allows monitoring health and accessing medical services, lowering the chances of progressing to severe Dengue.

People infected with Dengue can have symptoms that range from mild and asymptomatic (about 80%) to severe flu-like symptoms that can lead to death.

INTENDED USE

Turklab's Dengue NS1 Test is a rapid chromatographic immunoassay for the qualitative detection of Dengue NS1 antigen in whole blood, serum, or plasma.

- No cross-reactivity verified with HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, HCV, *H. Pylori*, MONO, CMV, Rubella, and TOXO positive controls.
- A wide range of samples can be used, including plasma, serum, capillary blood, or venous blood.

PERFORMANCE EVALUATION

Sensitivity:95,8%Specificity:96,3%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
DENGUE NS1	CASSETTE	WB/S/P	10 Min.	40	Test cassette + diluent +pipette instructions for use.



Dengue NS1, IgG/IgM TEST

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Detection of IgG/IgM in combination with NS1 antigen in the blood can help differentiate between primary and secondary infections as well as monitor the acute phase of Dengue infections.

The NS1 is found from Day 1 and up to Day 7 after the onset of fever in the sample of primary or secondary dengue-infected patients.

The IgM become detectable on Day 4 to 5 of illness in case of primary dengue infection and persist for several months. IgG, however, appears after IgM and may persist for life and rise both in primary and secondary infections but at much higher levels during secondary infections.

INTENDED USE

Turklab's Dengue NS1, IgG/IgM Test is a rapid chromatographic immunoassay for the qualitative detection of NS1 antigen, IgM, and IgG antibodies of Dengue virus in whole blood, serum, or plasma. This kit is intended to be used as a screening test and aid in diagnosing Dengue infections.

• Detects both IgG and IgM isotypes (types) as well as Dengue's NS1 antigen

PERFORMANCE EVALUATION

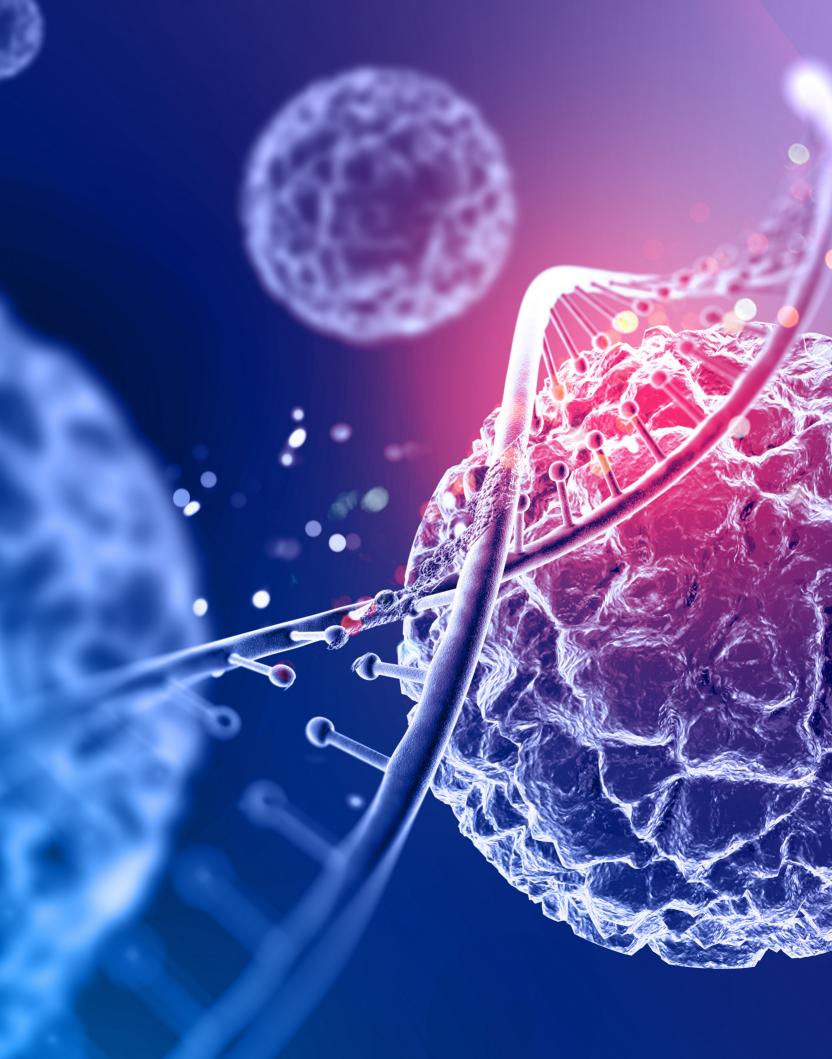
For IgG / IgM; For NS1;

Sensitivity: 95,8Specificity: 95,9%Specificity: 96,2%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
DENGUE NS1, IgG/IgM	CASSETTE	WB/S/P	10 Min.	40	Test cassette + diluent + instructions for use.





TUMOR MARKER TESTS

The presence of blood in the stool is an abnormal condition indicative of disease states of the gastrointestinal system, and multiple studies have shown a strong correlation between collorectal cancer (CRC) and rectal bleeding.

The use of rapid tests to verify the presence of blood in stool is very important as blood may not always be visible to the naked eye.

There are two common rapid methods for the detection of hidden blood in stool. The first uses the chemical Guaiac to produce color in the presence of heme in blood, called Guaiac fecal occult blood test (gFOBT).

The second is a chromatographic immunoassay that uses spesific antibodies to detect blood in stool, this method is called Immunochemical fecal occult blood test (iFOBT) or Faecal immunochemical testing (FIT).



FECAL OCCULT BLOOD (FOB) TEST



The presence of occult (hidden) blood in stool is associated with gastrointestinal disorders such as diverticulitis, polyps, Inflammatory bowel disease (such as Crohn's disease), hemorrhoids, as well as colorectal cancer (CRC).

Early diagnosis by fecal occult blood screening and treatment of these problems has been shown to reduce mortality from colorectal cancer significantly.

The use of specific antibodies to detect the presents of human hemoglobin in feces makes the test more accurate and sensitive than traditional methods.

INTENDED USE

Turklab's Fecal Occult Blood (FOB) Test is a qualitative immunochromatographic test detecting human hemoglobin (hHb) in human feces for professional use.

- The test kit contains all the compenents required for performing the test, includig an applicator rod with twisted collection ends.
- Can detect the presence of very low amounts of occult blood in stool. 10 ng/mL, or 50 ng/mL.
- Verified to show no cross interference with animal blood (dog, cattle, sheep, pig, goat, horse, rabbit.)

PERFORMANCE EVALUATION

For 10 ng hHb/ml Cut off value: For 50 ng hHb/ml Cut off value:

Sensitivity: 99,9%Specificity: 97,0%Specificity: 99,9%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
FOB	CASETTE	FECES	10 Min.	40	Test cassette+ sample collection tubes with dilution buffer + instructions for use.



GIKAN TEST

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The heme group of blood (hemoglobin in particular) in the presence of hydrogen peroxide oxidizes alpha-guaiaconic acid (a component of guaiac resin, a substance produced from the *Guaiacum* tree species) to blue-green colored quinone within 30-180 seconds.

The card test contains a special filter paper impregnated with natural guaiac resin and a color reagent containing hydrogen peroxide.

The blue-green color produced after the addition of hydrogen peroxide helps in the detection of occult (hidden) blood.

INTENDED USE

Turklab's Gikan card test is a card test for the qualitative detection of occult (hidden) blood in stool as an aid in the detection and diagnosis of gastrointestinal diseases.

PERFORMANCE EVALUATION

Sensitivity: 96.0%Specificity: 95.0%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
GIKAN	CARDS	FECES	COLOR REACTIVE	100	Card Test Device + Color Reagent + Applicator + Instructions For Use





CARDIAC MARKER TESTS

Early detection of serious medical heart conditions is of great importance in saving lives. There are several heart-specific proteins released into the bloodstream after a cardiac injury which are collectively called Cardiac Markers and sometimes mistakenly called Cardiac Enzymes.

These proteins are used in the rapid detection as well as the monitoring of serious medical heart conditions such as myocardial infarction (known as a heart attack).



Troponin I TEST

((

Troponin I is a regulatory protein part of the troponin complex which plays a vital part in non smooth muscle contraction (skeletal and cardiac).

The cardiac isoform of troponin-I (cTnI) is only expressed in cardiac muscle. Cardiac Troponin I is principally trapped within cardiac muscle cells (although minute amount of troponin is present in the blood stream in regular healthy state) and the leakage (release) of high amounts of cardiac troponin in the blood stream indicates cardiac injury.

Elavated cTnI levels are now widley considered as the standard biochemical marker for the diagnosis of myocardial infarction (commonly known as heart attack), a deadly medical emergency charachtrized by heart muscle cells death due to loss of oxygen reaching the heart.

The release of Tropinin I into the blood stream starts 4-6 hours after cardiac injury and remains high for up to 2 weeks thus providing for a long window of detection for cardiac injury as well as monitering already exisiting heart conditions.

INTENDED USE

Turklab's Troponin I Test is a immunochromatographic test for the qualitative detection of human cardiac marker Troponin I (cTnI) in human whole blood / serum / plasma to aid diagnosis of myocardial infarction (MI).

- Wide range of samples can be used, plasma, serum, capillary blood, or venous blood.
- Verified non-reactivity with skletal Troponin I, Troponin T and cardiac myosin.

PERFORMANCE EVALUATION

Sensitivity: 99,0%Specificity: 98,9%





PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
TROPONIN I	CASSETTE	WB/S/P	10 Min.	40	Test cassette + pipette + diluent + instructions for use.



Myoglobin/CK-MB/Troponin I Test



Myoglobin, creatine kinase (CK-MB), and Troponin I are the three most common cardiac markers.

Myoglobin is a hemeprotein typically found in skeletal and cardiac muscle and is responsible for transporting oxygen within muscle cells. Due to its small size, Myoglobin levels rise quickly (within two hours) of muscle injury, peak in 10 hours, and return to baseline within 24-36 hours.

However, since it is not specific to cardiac muscles, results need confirmation with other cardiac markers.

Creatine kinase (CK) is an enzyme that converts creatine to phosphocreatine using Adenosine triphosphate (ATP) and vice versa. CK is expressed in various tissues (especially tissues consuming ATP rapidly) in the human body.

CK-MB (Cardiac specific) levels elevate more slowly (3-12 hours), peak in 9 to 30 hours, and remain elevated before it returns to baseline levels within 48 to 72 hours.

The difference in the periods in which each of Myoglobin, CK-MB, and Troponin I rise provides an excellent and wide window for identifying heart conditions.

Observing the levels of these proteins is vital in the treatment process as well.

INTENDED USE

Turklab's Myoglobin / CK-MB / Troponin I Test is a immuno-chromatographic test for the qualitative detection of human cardiac marker Myoglobin, CK-MB and Troponin I in human whole blood / serum / plasma to aid diagnosis of myocardial infarction (MI).

- Simultaneos sensetive detection of 3 important cardiac markers.
- Verified (tested, established) non-reactivity with skletal Troponin I, Troponin T, CK-MM, CK-BB, and cardiac myosin.

PERFORMANCE EVALUATION

For Myoglobin: For CK-MB: For Troponin I;

- Sensitivity: 99,9% Sensitivity: 99,9% Sensitivity: 99,4%
- • Specificity: 98,0% • Specificity: 99,7% • Specificity: 98,2%



PRODUCT	TEST TYPE	SAMPLE TYPE	READING TIME	KIT SIZE	KIT COMPONENTS
Myoglobin / CK-MB / Troponin I	CASSETTE	WB/S/P	10 Min.	40	Test cassette + pipette + diluent + instructions for use.





PREGNANCY TESTS

Pregnancy tests are an easy and accurate way to find out the pregnant state. During pregnancy, several hormones with major roles are affected mostly. Significant changes in levels of HCG (Human chorionic gonadotropin hormone), estrogen, progesterone, and hPL (Human placental lactogen) are seen.

Early discovery has significant benefits for both mother and fetus. In the past, women became aware of their pregnancies only when the organogenesis of the fetus was almost concluded. Now, it is possible to detect pregnancy 11-15 days after conception.



hCG Pregnancy Cassette TEST

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HCG (Human Chorionic Gonadotropin), also called the pregnancy hormone, is made by cells formed in the placenta, which nourish the egg after it has been fertilized and becomes attached to the uterine.

As hCG appears shortly after conception both in serum and urine, the increase in concentration during the early stages of pregnancy provides this hormone as a perfect marker for the early determination of pregnancy. The measurement of hCG levels is important for identifying a normal pregnancy and pathologic pregnancy and can also be helpful following an aborted pregnancy.

HCG is a glycoprotein with 46 kDa molecular mass composed of 2 subunits: alpha (ahCG) and beta (βhCG) units. The beta subunit is unique to the hCG protein and is bigger than the alpha subunit, while the alpha subunit is identical to that for luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH).

INTENDED USE

Turklab's hCG Pregnancy Cassette Test is a rapid, immunochromatographic assay for the qualitative detection of human chorionic gonadotropin (hCG) hormone in human urine/serum to indicate pregnancy for professional use.

- Has been standardized to WHO International Standard.
- There is no Hook Effect (Measurement range up to 200.000 mIU hCG/mL)
- Accurate results with both urine and serum samples.

PERFORMANCE EVALUATION

Sensitivity: 99,4%

• Specificity:99,9%







BLOOD GROUPING

Transfusion Medicine is responsible for providing the highest safety level in blood transfusion. Blood transfusion can be a life saving intervention.

The purpose of pretransfusion testing is to select blood components that will not cause harm to the recipient and will have acceptable survival when transfused.

If performed properly, pretransfusion tests will confirm ABO compatibility between the donor and the recipient and detect most clinically significant unexpected antibodies.

TEST-IT Gel cards based on the column agglutination technique for blood typing and to identify the unexpected antibodies. Comprehensive TEST-IT Gel cards and reagents for performing pretransfusion compatibility testing provide timely and safe transfusion to the patients.

TEST-IT Gel cards offer a complete profile made up of costefficient and user friendly products for safe transfusion.



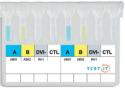


GEL CARDS

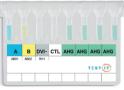


A B DVI+ C E CTL NAI NB

TEST-IT Gel
ABO/Rh(C,E) DVI+ & Reverse
REF TG105
CE 1434



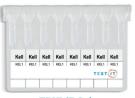
TEST-IT Gel Confirm ABO/DVI-REF TG109 CE 1434



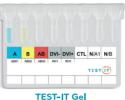
TEST-IT Gel Type / Screen REF TG113 CE 1434



TEST-IT Gel Rh Phenotype REF TG117 CE 1434



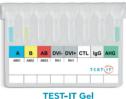
TEST-IT Gel Anti-Kell REF TG121 CE 1434



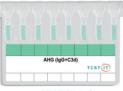
TEST-IT Gel
ABO/2D & Reverse
REF TG102
CE 1434



TEST-IT Gel
ABO/Rh(C,E) DVI- & Reverse
REF TG106
CE 1434



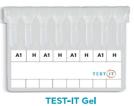
TEST-IT Ge Newborn REF TG110 CE 1434



TEST-IT Gel Coombs REF TG114 CE 1434



TEST-IT Gel
Rh Phenotype + Kell
REF TG118
CE 1434



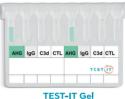
TEST-IT Gel ABO Type REF TG122 CE



TEST-IT Gel
ABO/CDE (DVI+) & Reverse
REF TG103
CE 1434



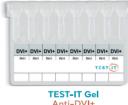
TEST-IT Gel
ABO/2D + Kell & Reverse
REF TG107
CE 1434



TEST-IT Gel DAT Screen REF TG111 CE 1434



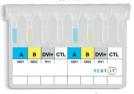
TEST-IT Gel Neutral REF TG115



TEST-IT Gel Anti-DVI+ REF TG119 CE 1434



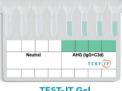
TEST-IT Gel
ABO/CDE (DVI-) & Reverse
REF TG104
CE 1434



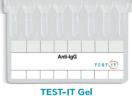
TEST-IT Gel
Confirm ABO/DVI+
REF TG108
CE 1434



TEST-IT Gel Cross Match REF TG112 CE 1434



TEST-IT Gel Neutral / Coombs REF TG116 CE 1434



TEST-IT Ge Anti-IgG REF TG120 CE 1434

PACKAGING TYPE	SHELF LIFE	STORAGE	
40 Cards	15 Months	2 – 25 °C	





REAGENTS AND SOLUTIONS

REFERENCE CODE	PRODUCT NAME	PACKAGING TYPE	SHELF LIFE	STORAGE	CE STATUS
TG301	TEST-IT LISS	100 ml	2 Years	2 - 25 °C	CE
TG302	TEST-IT LISS	500 ml	2 Years	2 - 25 °C	CE
TG303	TEST-IT Bromelin	30 ml	9 Months	2 - 8 °C	CE
TG304	TEST-IT Bromelin	100 ml	9 Months	2 - 8 °C	CE
TG305	TEST-IT Papain	10 ml	6 Months	2 - 8 °C	CE







TEST-IT LISS

Papain, Bromelin: Liquid Bromelin and Papain solutions for performing enzyme tests using gel techniques.

LISS: A reagent used for preparing red blood cell suspensions used in gel techniques.

REAGENT RED BLOOD CELLS RBC 0.8%

REFERENCE CODE	PRODUCT NAME	PACKAGING TYPE	SHELF LIFE	STORAGE	CE STATUS
TG201	TEST-IT Cell A1-A2-B-O	4 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG202	TEST-IT Cell Reverse A1-B	2 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG203	TEST-IT Cell Screen 2	2 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG204	TEST-IT Cell Screen 3	3 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG205	TEST-IT Cell Screen 4	4 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG206	TEST-IT Cell Screen 2P	2 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG207	TEST-IT Cell Screen 3P	3 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG208	TEST-IT Cell Screen 4P	4 x 10 ml	6 Weeks	2 - 8 °C	CE 1434
TG209	TEST-IT Cell Panel 11	11 x 5 ml	6 Weeks	2 - 8 °C	CE 1434
TG210	TEST-IT Cell Panel 11 P	11 x 5 ml	6 Weeks	2 - 8 °C	CE 1434
TG211	TEST-IT Cell Coombs Control	1 x 10ml	6 Weeks	2 - 8 °C	CE 1434
TG212	TEST-IT Cell Quality Control - 2	2 x 6 ml	6 Weeks	2 - 8 °C	CE
TG213	TEST-IT Cell Quality Control - 4	4 x 6 ml	6 Weeks	2 - 8 °C	CE



TEST IT CELL A1



TEST IT CELL B





MANUAL SYSTEMS

REFERENCE CODE	PRODUCT NAME	PACKAGING TYPE
TG401	TEST-IT Gel Centrifuge	1 × 1
TG402	TEST-IT Gel Incubator	1 × 1
TG403	TEST-IT Gel Reader	1 × 1
TG404	TEST-IT Gel Pipette	1 × 1
TG405	TEST-IT Gel Dispenser	1 × 1
TG406	TEST-IT Gel Workstation	1 × 1
TG407	TEST-IT Gel Pipette Tip	500 pcs/pack
TG408	TEST-IT Gel Test Tube	500 pcs/pack



TEST-IT GEL WORKSTATION Racks for tubes and gel cards.



TEST-IT GEL CENTRIFUGE
Gel card centrifuge for 24 cards

- * Predefined speed and time : 990 rpm 9 minutes
- \star LCD display shows remaining processing time
- * Removable and exchangeable spinning head
- $\ensuremath{\star}$ Electrical lid lock, over speed and imbalance protection.



TEST-IT GEL INCUBATOR
Gel card incubator for 24 cards.

- * 2 independent incubation zones (2x12)
- * Standard program: 15 minutes at 37 °C
- * Adjustable time
- * LCD display shows remaining processing time



TEST-IT GEL PIPETTE

- Dispensing volumes
- * 10 μ L to 40 pipetting
- * 25 μ L to 16 pipetting
- * 50 µL to 8 pipetting



DISPENSER 500µl

- * Fixed volume 500 μL
- * Attachable different types of bottles
- * Easy to use volume control

TEST-IT GEL READER GEL CARD READER



Barcode Systems:

* Identify TEST-IT Gel Cards by barcode Card code, card name and card barcode

* External barcode scanner Sample barcode and sample name

Software:

* Digitize and process card images

* Interpret results automatically

Data Management:

* Record and store data to ensure traceability

* Automated upload of results to LIS/HIS.

User Menu:

* Touch Screen

* Mini Printer

* USB Interface



TURKLAB MEDICAL DEVICES

HEADQUARTERS

ITOB 10017 Sk. No: 2 Menderes-Izmir-TURKIYE

FACTORY 2:

ITOB 10031 Sk. No:15 Menderes-Izmir-TURKIYE

FACTORY 3:

ITOB 10020 Sk. No:22/1 Menderes-Izmir-TURKIYE

FACTORY 4:

ITOB OSB 10001 Sk. No:2 Menderes-Izmir - TURKIYE

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