Enzyme immunoassays for the diagnosis of Infectious diseases

ELISA kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum or plasma

CE IVD Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Parasites and fungi

Aspergillus fumigatus is a fungus of the genus *Aspergillus*, and is one of the most common Aspergillus species to cause disease in individuals with an immunodeficiency. Aspergillosis develops mainly in individuals who are immunocompromised, either from disease or from immunosuppressive drugs, and is a leading cause of death in acute leukemia and hematopoietic stem cell transplantation. The term aspergillosis comprises a number of different diseases caused by fungi of the genus Aspergillus. The most common forms are allergic bronchopulmonary aspergillosis, pulmonary aspergilloma and invasive aspergillosis.

Allergic bronchopulmonary aspergillosis is characterized by an exaggerated response of the immune system to Aspergillus species. Aspergilloma, commonly referred to as "fungus ball," occurs in preexisting pulmonary cavities that were caused by tuberculosis, sarcoidosis, or other bullous lung disorders. Invasive aspergillosis is a rapidly progressive, often fatal disease, targeting severely immunocompromised patients, including those with hematological malignancies such as leukemia, those who have received solid organ or hematopoietic stem cell transplants, and individuals with chronic granulomatous disease or advanced AIDS.

Candida albicans is an ubiquitious present yeast like fungus belonging to the family of ascomycota. It is a facultative pathogen belonging to the normal microbial flora of skin and mucosa. Beside the yeast form which appears mainly with superficial infections, so called pseudomycelia are another morphological form of ascomycota. Pseudomycelia prevail with invasive mycosis. Although not pathogenic in healthy humans the fungus may be opportunistic in those suffering from a variety of disorders, and in those treated intensively with broad-spectrum antibiotics or immunosuppressive measures.

Candidiasis is caused to about 90% by C. albicans. It is an acute, superficial or subacute, invasive infection. Acute infections with the fungus may produce lesions in the mouth, vagina, skin and nails. Subacute infections may affect bronchi, lungs, heart or meningeal. In immunosuppressant patients with cellular immunodeficiency, e.g., AIDS patients, C. albicans may lead to severe necroses of infected tissues.

Echinococci are microscopic cestodes (tapeworms) of 1-6 mm which are dependent on their genus found either in dogs or other canids (*E. granulosus*) or in foxes, coyotes and wolves (*E. multilocularis*). In their larval stage they are the causative agent of human echinococcosis (Hydatiosis, or hydatic disease). The adult tapeworms reside in the small bowel of the definitive hosts, and gravid proglottids release eggs that are passed in the feces. After ingestion of a suitable intermediate host, the egg hatches in the small bowel and releases an oncosphere that penetrates the intestinal wall and through the circulatory system into various organs, especially the liver and lungs, where it develops into a cyst.

Echinococcus infections remain silent for years before the enlarging cysts cause symptoms in the affected organs (liver, lung, and less commonly other organs as brain, bone, heart). Although human cases are rare, infection in humans causes parasitic tumors to form in the liver, the lungs, and less commonly, the brain, and other organs. If left untreated, infection can be fatal.

Leishmania are protozoa belonging to the family trypanosomatidae. The parasites exist in two forms: the promastigotes in the midgut of the vector insect, and the amastigotes within the phagolysosomes of macrophages in their mammalian hosts. In humans four different forms of Leishmaniasis are present, with a broad range of clinical manifestations. All can have devasting consequences. Leishmaniasis currently affects some 12 million people in 88 countries, all but 16 of which are in the developing world.

Visceral leishmaniasis (VL) is the most severe form of the disease, which, if untreated, has a mortality rate of almost 100%. AIDS and other immunosuppressive conditions increase the risk of Leishmania infected people developing visceral illness (VL). Leishmania/HIV co-infections are considered to be a real "emerging disease", especially in south-western Europe, where 25–70% of adult VL cases are related to HIV infection, and 1.5–9.5% of AIDS cases suffer from newly acquired or reactivated VL. Intravenous drug users have been identified as the main population at risk.

Schistosomes belong to the class of distomas (trematodes). They rank among the most frequent pathogens. Estimations originate in more than 200 million affected people. The mature parasites are 6–22 mm long. The most important species are Schistosoma mansoni, S. japonicum and S. haematobium. Schistosoma mansoni is common in Africa, South America and Middle East.

Humans are (re)infected by contact with fresh water which is contaminated by ova containing urine or faeces. If larvae bore into human skin, first a transient skin reaction appears (itch with exanthema or erythema, by repeatedly infection cercarial dermatitis is possible). After 3–10 weeks the meanwhile sexually mature worms synthesize cytotoxic and allergic substances which course feverish reaction in humans (Katayama fever). The infected person is mostly harmed by the eggs, which get into organs via blood excreting proteins and glycoproteins. The person reacts under participation of own antibodies and immune complexes with formation of granuloma and granulomatous proliferation in intestine and urinary bladder mucosa.

Viruses and bacteria

Brucella is a small Gram-negative bacterium, of which four species are pathogenic to human: *B. abortus*, *B. melitensis*, *B. suis* and *B. canis*. All four species are exciters of *Brucellosis*, a disease characterized by undulating fever. Depending on exciter the disease is also called Morbus Bang (*B. abortus*) or Malta fever (*B. melitensis*).

The pathogens are transmitted from animals, which are mainly affected. The infection is caused by contact with ill animals or their excrements as well as by non-pasteurized milk and milk products like fresh cheese from sheep or goat. The incubation period is one to three weeks, but it can reach up to two months. *B. abortus* and *B. melitensis* can cause Bang disease or in rare cases the so-called Malta fever. Bang‘s disease occasionally appears in humans although with low pathogenicity. Typical symptoms of Bang‘s disease are periodic fever, hepatosplenomegaly and swollen lymph nodes. In some cases, inflammation of the joints and other organs may occur. Malta fever is caused by an epidemic strain of brucellosis. Infection almost always leads to manifest disease. Some brucella infections manifest such as Brucella hepatitis. A connection between Brucella infection and the development of multiple sclerosis is considered.

Risk groups include abattoir workers, meat inspectors, animal handlers, veterinarians, and laboratorians. Brucellosis is common mainly during spring and winter months.

Legionellae are aerobic Gram-negative facultative intracellular parasites of certain protozoa. They are found in freshwater environments worldwide and can cause respiratory disease (legionellosis) in humans. Legionellosis can be acquired by the inhalation of aerosols containing Legionella bacteria or by micro-aspiration of ingested water contaminated with Legionella. Person-to-person transmission is not thought to be a risk.

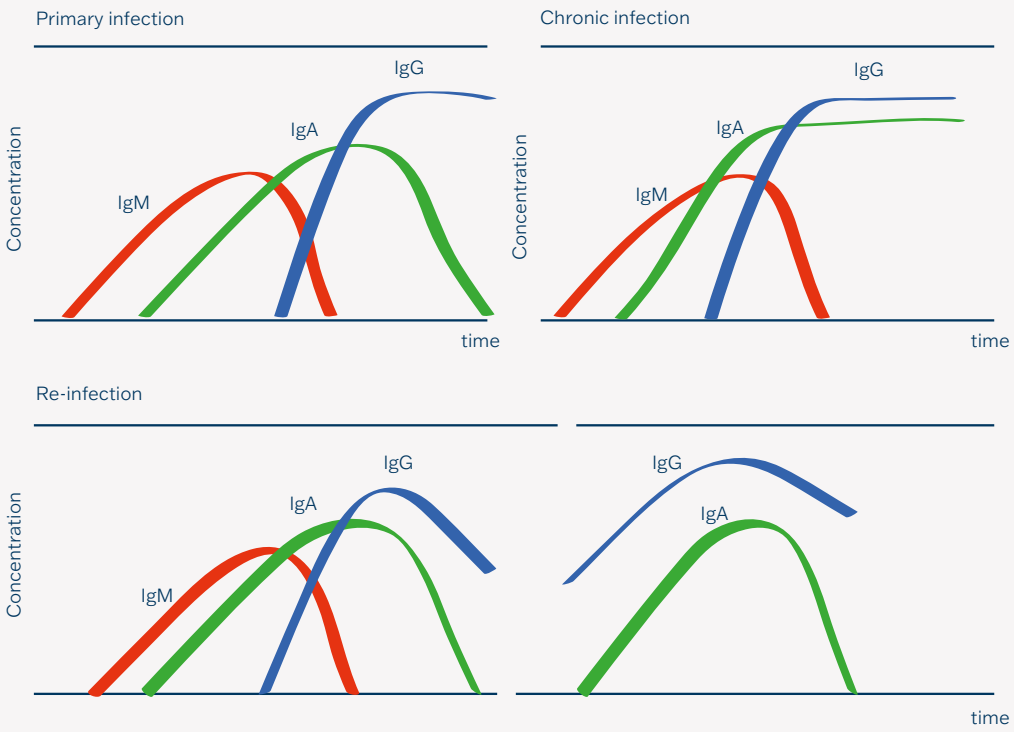
Legionellosis can appear in two distinct clinical presentations: *Legionella pneumonia* (Legionnaires’ disease) with an incubation period of approx. 2–10 days (may extend up to 16–20 days) and Pontiac fever (incubation period: normally 12–48 hours). *Legionella pneumonia* (Legionnaires’ disease) is a serious form of pneumonia that carries with it a case-fatality ratio of 10–15 %. Legionnaires’ disease patients initially present with cough, fever and nonspecific symptoms including malaise,

myalgia and headache. Some patients develop shaking chills, chest pain, diarrhea, delirium or other neurologic symptoms. Extra pulmonary involvement is rare.

Pontiac fever is a milder form of the disease without manifestations of pneumonia and presents as an influenza-like illness. Symptoms may include headache, chills, muscle aches, a dry cough and fever. It is usually self-limiting and typically does not require treatment. The attack rate is much higher than for Legionnaires' disease (up to 95 % of those exposed).

Antibody response

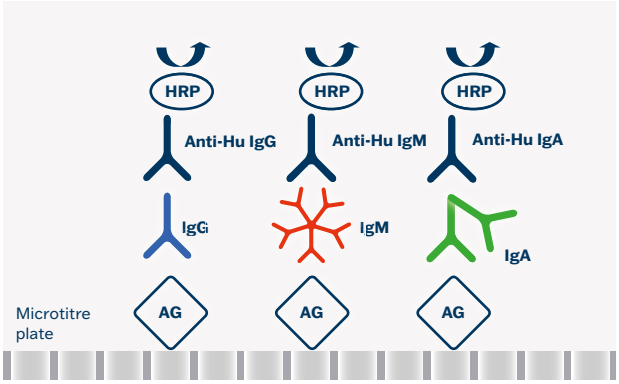
Schematic antibody response dynamics



ELISA

Test Principle

The assays are based on a sandwich type of ELISA method.



Summary Protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette Controls and diluted samples 100 µl – Blank = empty well
	3.	Incubate 60 min. at 37 °C
	4.	Aspirate and wash the wells 3 times
	5.	Add Conjugate 100 µl – Blank = empty well
	6.	Incubate 30 min. at room temperature
	7.	Aspirate and wash the wells 3 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 15 min. at room temperature in dark
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

User Comfort

- Ready-to-use components
- Colour-coded components
- Interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF and controls included
- Semi-quantitative evaluation
- Easy assay procedure

Advantages

- Identical assay procedure
- High diagnostic specifity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Short total assay time
- Ready for automation
- Customer support

Test Characteristics

ELISA	Diagnostic Sensitivity	Diagnostic Specificity
Aspergillus fumigatus IgG ELISA	95.7%	100.0%
Aspergillus fumigatus IgM ELISA	100.0%	90.9%
Brucella IgG ELISA	98.8%	100.0%
Brucella IgM ELISA	100.0%	100.0%
Candida albicans IgA ELISA	100.0%	100.0%
Candida albicans IgG ELISA	100.0%	96.7%
Candida albicans IgM ELISA	100.0%	100.0%
Echinococcus IgG ELISA	98.8%	97.2%
Legionella pneumophila IgG ELISA	100.0%	90.0%
Legionella pneumophila IgM ELISA	95.7%	100.0%
Leishmania infantum IgG ELISA	92.6%	90.9%
Schistosoma mansoni IgG ELISA	98.6%	93.8%
Schistosoma mansoni IgM ELISA	96.2%	92.6%

Ordering Information

ELISA

Cat. No.	Product	No. of Wells
AfG096	Aspergillus fumigatus IgG ELISA	96
AfM096	Aspergillus fumigatus IgM ELISA	96
BruG96	Brucella IgG ELISA	96
BruM96	Brucella IgM ELISA	96
CaA096	Candida albicans IgA ELISA	96
CaG096	Candida albicans IgG ELISA	96
CaM096	Candida albicans IgM ELISA	96
EchG96	Echinococcus IgG ELISA	96
LpG096	Legionella pneumophila IgG ELISA	96
LpM096	Legionella pneumophila IgM ELISA	96
LiG096	Leishmania infantum IgG ELISA	96
SmG096	Schistosoma mansoni IgG ELISA	96
SmM096	Schistosoma mansoni IgM ELISA	96

MADE IN COOPERATION

TestLine®

NovaTec Immundiagnostica GmbH

TestLine Clinical Diagnostics Ltd.
Krizikova 68, 612 00 Brno
Czech Republic
+420 549 121 203
sales@testlinecd.com
www.testlinecd.com

V11/2022