

Infectious Diseases ELISAS

DRG

Treponema
Dengue
Ureaplasma urealyticum
Echinococcus
Fasciola
Mycoplasma hominis
and more



DRG

DRG Diagnostics

DRG Instruments GmbH, founded in 1973 by Dr. Geacintov, a subsidiary of DRG Intl. Inc., USA, is a diagnostics manufacturer and distributor with successful operations in over 100 countries. The DRG Group focuses on high technology medical diagnostic areas such as Diabetes Diagnosis, Gynecology, Oncology, Immunology, Infectious Diseases and Toxicology. The highly skilled DRG Staff of medical, clinical, marketing and service specialists are experts at taking innovative technology to market through local territory knowledge and contacts, end-user training, education and cost effective financial and logistical support. The DRG-Development and Immunoassay production facilities are located in Marburg, Germany, in addition to OEM manufacturing in the USA.

A range of new, occasionally unique ELISA kits has been developed. The DRG ELISA kits compete effectively in both price and performance in all major world diagnostics markets.

To complete the diagnostic reagent line, DRG supplies the clinical laboratory with all necessary equipment, including a semi-automatic microtiterplate processor, the DRG E-LizaMat 3000, and fully automated Open System for 2 microtiterplates, which are fully compatible with all Elisas.

DRG launched the FIRST fully automated random access Analyzer for Immunoassays, Clinical Chemistry and Immunoturbidimetry, the

DRG:HYBRID•XL®

The DRG Group operates through a network of DRG subsidiaries in Germany, Poland, Russia, China and the Czech Republic, and through distributors in Europe, the Middle East, Africa and the Pacific Region. This infrastructure offers access to specialized medical markets in most major countries around the world.

ELISAS that perform DRG

DRG develops, manufactures diagnostic ELISA test kits for use in clinical and research laboratories.

The experience of our production and management team guarantees to provide high quality products, competitive prices and excellent customer service.

DRG-NOVUM ELISAS

At the end of 2003 DRG has taken over the assets of Novum Diagnostica, Dietzenbach. Novum has developed and manufactured a wide range of products to identify and manage infectious diseases.

Now DRG is manufacturing these ELISAS in the same excellent quality and offers these assays at competitive prices.

Production Facility, Marburg

Quality

DRG works to DIN EN ISO 9001:2008 and ISO 13985 2003 under CMD CAS standard, certified by TÜV Rheinland Product Safety GmbH, an indication of our commitment to customer service, quality control and improved health care.

We participate in a number of quality assessment schemes, which include Instand (Germany) and RfB, Referenzinstitut für Bioanalytik, Bonn.

DRG products meet the essential requirements of the Directive 98/79/EC on in-vitro diagnostic medical devices.



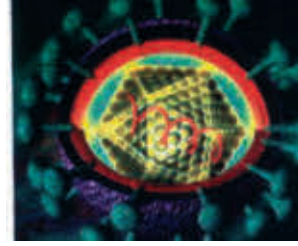
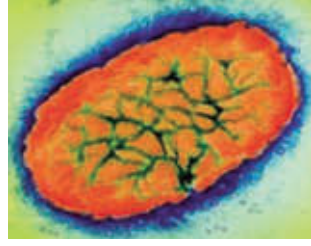
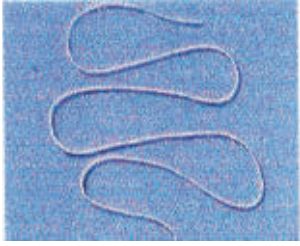
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NEW ELISAS

- Coxiella (Q-fever)
- Fasciola IgG
- Hanta Virus
- Mycoplasma hominis IgA/IgG/IgM
- Rickettsia conorii IgG/IgM
- Ureaplasma urealyticum IgA/IgG/IgM

Infectious Diseases ELISAS



Content

| Parasites | page | Bacteria | page | Virus | page | Fungi | page |
|------------------------------------|------|------------------------------------|------|---|------|-----------------------|------|
| Ascaris lumbricoides | 4 | Bordetella pertussis | 5 | Adenovirus | 4 | Aspergillus fumigatus | 4 |
| Cryptosporidium | 8 | Borrelia burgdorferi (Lyme) | 5 | Astrovirus | 4 | Candida albicans | 6 |
| Echinococcus | 9 | Brucella | 5 | Chikungunya | 6 | | |
| Entamoeba histolytica | 9 | Campylobacter | 5 | Coxsackie Virus | 7 | | |
| Fasciola | 10 | Chlamydia | 6 | Cytomegalovirus (CMV) | 8 | | |
| Giardia lamblia | 10 | Clostridium difficile toxin | 7 | Dengue Virus | 8 | | |
| Leishmania | 13 | Corynebacterium diphtheria | 7 | Epstein-Barr Virus (EBV) | 9 | | |
| Malaria | 13 | Coxiella burnetii | 7 | Hanta Virus | 11 | | |
| Schistosoma mansoni | 17 | E.coli | 10 | Hepatitis Virus | 11 | | |
| Strongyloides | 17 | Haemophilus influenzae | 10 | Herpes Simplex Virus (HSV) | 11 | | |
| Taenia solium | 17 | Helicobacter pylori | 11 | Human Papilloma Virus | 12 | | |
| Toxocara canis | 18 | Legionella pneumophila | 13 | Influenza A and B Virus | 12 | | |
| Toxoplasma gondii | 18 | Leptospira | 13 | Japanese Encephalitis | 12 | | |
| Trichinella spiralis | 18 | Mycobacterium tuberculosis | 14 | Measles Virus | 13 | | |
| Trypanosoma cruzi (Chagas Disease) | 19 | Mycoplasma hominis | 14 | Mumps Virus | 14 | | |
| | | Mycoplasma pneumoniae | 15 | Norovirus | 15 | | |
| | | Rickettsia conorii | 16 | Parainfluenza 1/2/3 Virus | 15 | | |
| | | Tetanus (Clostridium tetani) toxin | 17 | Parvovirus B19 | 15 | | |
| | | Treponema pallidum (Syphilis) | 18 | Poliomyelitis | 16 | | |
| | | Tuberculosis (TB) | 14 | Respiratory Syncytial Virus (RSV) | 16 | | |
| | | Ureaplasma urealyticum | 19 | Rotavirus | 16 | | |
| | | Yersinia enterocolitica | 19 | Rubella Virus | 16 | | |
| | | | | Tick-borne encephalitis (TBE, FSME) Virus | 17 | | |
| | | | | Varicella Zoster Virus | 19 | | |
| | | | | West Nile Virus | 19 | | |

Please ask for our Rapid Test Panel!

Adenovirus

V

Adenoviruses are double-stranded DNA viruses of about 60-90 nm lacking an envelope. The capsid contains 252 capsomeres and shows icosahedral symmetry. The capsomeres consist of hexons, pentons, and fibers (so named after their configuration) which are responsible for the induction of group- and type-specific antibodies. 34 immunologically distinct types (serotypes) are recognized in man.

Adenoviruses were first isolated from adenoid tissue and have certain affinity for lymph glands, where they may remain latent for years. They also invade the respiratory tract, the gastrointestinal tract, and the conjunctiva. Adenovirus infections are widely distributed and common with most infections occurring in childhood. The contagious disease normally is acute and self-limited, but infections may be prolonged and asymptomatic, possibly remaining latent for a very long time. Seasons for highest rates of general adenovirus infections are winter and spring, independent of geographic locations and climatic conditions. Epidemics may occur in populations crowded together, for example ARD in military groups, PCF in swimming pools, and EKC in medical facilities.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|------------------------------------|----------|-------------------|--|----------------|---------------------|-----------------|----------|
| Adenovirus IgA ELISA | EIA-3445 | 60/30/15 | Qualitative | | Serum 10 µl /Plasma | 1:101 | |
| Adenovirus IgG ELISA | EIA-3446 | 60/30/15 | Qualitative | | Serum 10 µl /Plasma | 1:101 | |
| Adenovirus IgM ELISA | EIA-3447 | 60/30/15 | Qualitative | | Serum 10 µl /Plasma | 1:101 | |
| Adenovirus Ag (stool) ELISA | EIA-3444 | 30/5/5/5 | Qualitative | | Stool 100 µl | 1:5 | |



Ascaris lumbricoides

P

Ascariasis is an infection caused by a parasitic roundworm, *Ascaris lumbricoides*. This is the most common intestinal worm infection. It is found in association with poor personal hygiene, poor sanitation, and in places where human feces are used as fertilizer. Intake of food or drink contaminated with roundworm eggs causes infection.

The eggs hatch and release larvae within the intestine. The larvae then move through the bloodstream to the lungs, exit up through the large airways of the lungs, and are swallowed back into the stomach and intestines. During movement through the lungs the larvae may produce an uncommon form of pneumonia called eosinophilic pneumonia. Once back in the intestines, they mature into adult roundworms. Adult worms live in the intestine where they lay eggs that are present in feces.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------------------|----------|-------------------|--|----------------|---------------|-----------------|----------|
| Ascaris lumbricoides IgG ELISA | EIA-3817 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |

Aspergillus fumigatus

F

The most common pathogen of the genus *Aspergillus* is *A. fumigatus* occurring in hay, grain, rotten plants and bird faeces. The main opportunistic invasive fungal infections are the candidal mycosis followed by aspergillosis. In general infections with *Aspergillus* spp. are airborne. Because of the ubiquity of *Aspergillus* species it is difficult to decide between contamination by commensalism or a serious infection. Usually infection in humans occurs in already damaged tissues only. *Aspergillus* spp. can cause a chronic infection of paranasal sinus, eyes or lungs.

Three types of lung-aspergillosis can be distinguished: acute infection (bronchial pneumonia; pneumonia), saprophytic aspergillom (compact reticulum of hyphae in the lungs) and allergic bronchopulmonary aspergillosis (mediated by IgE).

Next to the ELISA the indirect *Aspergillus* hemagglutination test (*Aspergillus* HAT) can be performed to detect specific IgG and IgM antibodies. The HAT is not suitable as a screening test, however, because of its low sensitivity. In some high-risk patients it shows only low antibody titers.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|--|----------------|-------------------|-----------------|----------|
| Aspergillus fumigatus IgA ELISA | EIA-2500 | 60/30/20 | Quantitative | 1-140 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Aspergillus fumigatus IgG ELISA | EIA-2501 | 60/30/20 | Quantitative | 1-200 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Aspergillus fumigatus IgM ELISA | EIA-2502 | 60/30/20 | Quantitative | 1-60 U/ml | Serum/Plasma 5 µl | 1:101 | |

Astrovirus

V

Astrovirus was firstly described in 1975 and named according to its star-shaped structure visible under the electron microscope.

Astrovirus belongs to the family Astroviridae. Human Astroviruses are subdivided into 7 serotypes.

Together with Rotavirus and Adenovirus Astrovirus is one of the most common causes of nonbacterial gastroenteritis in children under 5 years of age all over the world. Thus 80% of children between 5 and 10 years of ages are anti-Astrovirus-antibody positive. Astrovirus caused gastroenteritis in adults and nosocomial infections are observed as well.

The course of the disease is usually self-limiting and of short duration. After the incubation time of 1-2 days a 1-4 days lasting gastroenteritis develops accompanied by vomiting, diarrhea, fever and abdominal pain finally causing dehydration. Although occurring all over the year Astrovirus infections are mainly observed during the winter months.

Astrovirus infections are spread via faecal-oral transmission from person to person or via contaminated things or food. Infected persons excrete high amounts of Astrovirus particles with their faeces.

The detection of Astrovirus may be performed by electron microscopy or by molecular biology techniques such as polymerase chain reaction (PCR). Meanwhile immunological methods like enzyme immunoassay have established as preferential methods for routine laboratory diagnosis since these methods are fast, economical and automation is possible.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|------------------------------------|----------|-------------------|--|----------------|----------------------|-----------------|----------|
| Astrovirus Ag (stool) ELISA | EIA-4456 | 60/10 | Qualitative | | Stool 100 µl/ 100 mg | 1:1 | |

Bordetella Pertussis B

Bordetella species are non-spore-forming encapsulated bipolar, coccoid (pale-staining) Gram-negative bacilli (about 0.3-0.5 µm thick and 1 µm long). The genus consists of the human parasites *B. pertussis* and *B. parapertussis*, and *B. bronchiseptica* which causes enzootic infections in various wild and domestic animal species. *Bordetella pertussis* produces a single disease syndrome in man known as pertussis or whooping cough. It is a highly contagious childhood disease (app. 80% of cases occur before the age of 5 years) which is transmitted by respiratory contact and is associated with a high mortality rate (about 1-2% in the first year of life, later on about 0.1 %). In the absence of immunization, essentially no one escapes pertussis. Clinical pertussis is followed by natural acquired immunity which is long-lasting but not permanent. The distribution of the disease is worldwide, though clearly modified by immunization and other poorly defined social, economic, and nutritional factors. In most countries an active vaccination is recommended. Usually the immunization preparation is combined with diphtheria and tetanus toxoids.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|--|----------------|---------------|-----------------|----------|
| Bordetella pertussis/toxin IgA ELISA | EIA-3449 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Bordetella pertussis/toxin IgG ELISA | EIA-3450 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Bordetella pertussis/toxin IgM ELISA | EIA-3451 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |

Borrelia burgdorferi (LYME) B

Borrelia burgdorferi, a bacterium of the Spirochaetaceae, is the etiologic agent of Lyme disease (Borreliosis) being the most common disease in Europe and the USA transmitted by ticks (*Ixodes* sp.). Lyme borreliosis is a multi-systemic disease with a broad spectrum of clinical symptoms. A typical symptom of the acute phase is the erythema chronicum migrans (ECM), often accompanied by flu-like symptoms. In later stages of the disease arthritis, carditis, as well as neurological and dermatological manifestations may occur. Lyme borreliosis can be treated with antibiotics in all stages. Therefore, a safe and sensitive laboratory diagnosis of Lyme borreliosis, also detecting the early stage of diseases, is of major importance, since an early treatment is most appreciated. IgM antibodies usually appear approximately three weeks after the infection. IgG antibodies after four to six weeks. The early immune reaction is mainly directed against the flagellin peptide (41 kDa) and the OspC (Outer surface protein C, 23 kDa) and is then spread on more and more bacterial proteins. Usually the acute phase is indicated by high titers of IgM antibodies. Elevated IgG titers with low or without IgM antibodies may occur when the borreliosis is subsiding (due to therapy or spontaneously) or during the chronic stage. The performance of the *Borrelia* IgG ELISA is important especially to detect a borreliosis even in cases showing negative 14 kDa + OspC titers and to monitor the immune status. The *Borrelia* IgG ELISA employs the very highly specific recombinant *Borrelia burgdorferi* VlsE antigen and a highly specific crude lysate antigen blend from *Borrelia burgdorferi sensu strictu*, *B. afzelii* and *B. garinii* and therefore determines IgG antibodies with extremely high sensitivity and specificity.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|-----------------------------|----------------|---------------------------------|-----------------|----------|
| Borrelia IgG + VlsE ELISA | EIA-4289 | 60/30/30 | Quantitative | 2-200 U/ml | Serum, Plasma, CSF 10 µl, 50 µl | 1:101 1:4 | |
| Borrelia 14 KD + OspC IgM ELISA | EIA-4288 | 60/30/30 | Quantitative | 2-100 U/ml | Serum, Plasma, CSF 10 µl, 50 µl | 1:101 1:4 | |
| Anti-Borrelia LIA IgG | EIA-5300 | 5/45/45/10 | Qualitative | | Serum 15 µl /Plasma | | 20 tests |
| Anti-Borrelia LIA IgM | EIA-5301 | 5/45/45/10 | Qualitative | | Serum 15 µl /Plasma | | 20 tests |

(LIA = Line Immuno Assay)



Brucella B

Brucella is a small gram-negative bacterium (0.4-0.8 µm in diameter and 0.4-3.0 µm in length) which is non-flagellated, and non-spore-forming. Since the discovery of *Brucella melitensis* by Bruce in 1887, an increasingly complex pattern of strains has emerged, and each type has distinctive epidemiological features. Virulent *Brucella* organisms can infect both nonphagocytic and phagocytic cells; the mechanisms of pathogenesis of Brucellosis in its natural host species and in humans are still not completely understood. Worldwide, brucellosis remains a major source of disease in humans and domesticated animals. Although reported incidence and prevalence of the disease vary widely from country to country (from <0.01 to >200 per 100,000 population), bovine brucellosis caused mainly by *B. abortus* is still the most widespread form. Risk groups include abattoir workers, meat inspectors, animal handlers, veterinarians, and laboratorians. Brucellosis is a nationally notifiable disease and reportable to the local health authority.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------|----------|-------------------|--|----------------|--------------------|-----------------|------------------|
| Brucella IgA ELISA | EIA-3271 | 60/30/20 | Quantitative | 1-200 U/ml | Serum/Plasma 5 µl | 1:101 | min-Order 5 Kits |
| Brucella IgG ELISA | EIA-3455 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Brucella IgM ELISA | EIA-3456 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Campylobacter B

Infection by thermophilic *Campylobacter* species is a leading cause of human gastroenteritis. Of the various species of *Campylobacter* are *C. jejuni*, *C. coli* and *C. lari* the species most often associated with human illness. *Campylobacter* is often passed to humans through the handling or consumption of contaminated food, particularly foods of animal origin. Recently, human infection with *Campylobacter* has been implicated in the induction of Guillain-Barré Syndrome (GBS) and reactive arthritis. GBS is a debilitating and potentially fatal neurological disease that produces paralysis. *Campylobacter* species are gram negative, motile curved or spiral rods that require highly specialized growth conditions. Typical cultivation entails pre-enrichment and enrichment steps in broth, followed by isolation on a selective solid medium. Of particular importance in the cultivation of *Campylobacter* is the requirement for a microaerobic atmosphere.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution |
|---------------------------------------|----------|-------------------|--|----------------|--------------------|-----------------|
| Campylobacter Ag (stool) ELISA | EIA-4518 | 30/15/5 | Qualitative | | Stool 0.1 g/0.1 ml | 1:4 |

Candida albicans F

Species of *Candida* are non-mycelia-producing non-ascospore-forming yeastlike fungi which appear as small (4–6 µm), oval, thin-walled gram-positive budding cells. The most important representative, *Candida albicans*, is a facultative pathogen for man. *C. albicans* is ubiquitous and commonly found as transient flora on normal mucous membranes. 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 or subacute infection in which the fungus may produce lesions in the mouth (thrush, oral candidiasis), vagina (vulvovaginal candidiasis), skin and nails (intertriginous candidiasis), bronchi or lungs (bronchopulmonary candidiasis) and, occasionally, a septicemia, endocarditis or meningitis. In immunosuppressed patients with cellular immunodeficiency, e.g., AIDS patients, *C. albicans* may lead to severe necroses of infected tissues.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-----------------------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Candida albicans IgA ELISA | EIA-3457 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Candida albicans IgG ELISA | EIA-3458 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Candida albicans IgM ELISA | EIA-3459 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |

Chikungunya V

Chikungunya virus is an arthropod borne virus of the genus *Alphavirus* (family *Togaviridae*). The *Alphavirus* genus contains at least 24 distinct species. These are lipid-enveloped virions with a diameter of 50 to 60 nm. *Alphavirus* infections are initiated by the bite of an infected mosquito, which results in the deposition of virus in subcutaneous and possibly cutaneous tissues. After an incubation period of 1 to 12 days the Chikungunya fever develops. Chikungunya fever (Chikungunya means „that which bends up“, in reference to the crippling manifestations of the disease) is an acute viral infection characterized by a rapid transition from a state of good health to illness that includes severe arthralgia and fever. Temperature rises abruptly to as high as 40°C and is often accompanied by shaking chills. After a few days, fever may abate and recrudescence, giving rise to a „saddleback“ fever curve. Arthralgia is polyarticular, favoring the small joints and sites of previous injuries, and is most intense on arising. Patients typically avoid movement as much as possible. Joints may swell without significant fluid accumulations. These symptoms may last from 1 week to several months and are accompanied by myalgia. The rash characteristically appears on the first day of illness, but onset may be delayed. It usually arises as a flush over the face and neck, which evolves to a maculopapular or macular form that may be pruritic. The latter lesions appear on the trunk, limbs, face, palms and soles, in that order of frequency. Petechial skin lesions have also been noted. Headache, photophobia, retro-orbital pain, sore throat with objective signs of pharyngitis, nausea and vomiting also occur in this setting. Occasionally, however persistent arthralgia and polyarthritis (lasting months or even years) do occur, sometimes involving joint destruction. Even rarer, sequelae include encephalitis and meningoencephalitis with high lethality rates. The virus has major importance in Africa and Asia. From 20% to more than 90% of the population of tropical and subtropical show serologic evidence of infection. Because *Aedes* mosquitoes are increasingly prevalent in North Africa and South America, where the population would be uniformly susceptible to infection, the possibility for epidemics is evident. Chikungunya virus infections are imported to central Europe mainly by travellers to tropical and subtropical countries.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Sample Volume | Sample Dilution | Specials |
|------------------------------|----------|-------------------|---|--------------------|-----------------|----------|
| Chikungunya IgG ELISA | EIA-5102 | 60/30/30/30/15 | Qualitative | Serum/Plasma 10 µl | 1:101 | |
| Chikungunya IgM ELISA | EIA-5103 | 60/30/30/30/15 | Qualitative | Serum/Plasma 10 µl | 1:101 | |

Chlamydia B

Chlamydiae are non-motile, Gram negative and obligatory intracellular growing bacteria which form characteristic inclusions within the cytoplasm of parasitized cells. They are easily visible in the light microscope.

Three different *Chlamydia* species pathogenic for humans are known: *Chlamydia trachomatis*, *Chlamydia pneumoniae* and *Chlamydia psittaci*, and one species only pathogenic for animals (*C. pecorum*).

Chlamydia trachomatis is the most prevalent agent of sexually transmitted diseases worldwide (400-500 million cases) and the number of infections is constantly growing. Rates in sexually active young people are commonly between 5 % and 10 % in Europe. In women, *Chlamydia trachomatis* can lead to pelvic inflammatory disease (PID), tubal infertility and ectopic pregnancy. Infection during pregnancy is associated with premature rupture of the membranes, low birth weight and miscarriage. *Chlamydia trachomatis* can also be transmitted from mother to baby during labour, causing eye and respiratory infections. In men, *Chlamydia trachomatis* can lead to acute genital inflammation (epididymitis, epididymo-orchitis) and occasionally to sexually-acquired reactive arthritis (SARA). In men and women *Chlamydia trachomatis* may produce proctitis. Individuals with *Chlamydia trachomatis* are at increased risk of acquiring or transmitting HIV. Extraarticular infection with *Chlamydia trachomatis* caused an inflammatory reactive arthritis (*Chlamydia*-induced arthritis (CIA)).

A severe problem in *Chlamydia* infections is the frequent asymptomatic insidious course which may result in the initiation of chronic diseases. In many instances primary infections are not recognized and only the sequelae caused by ascended, persisting agents are diagnosed.

Infection can be identified by Microscopy (Giemsa stain), PCR, Serology: Detection of antigens by ELISA, detection of antibodies by IF, EIA, ELISA.

After primary infection, IgM, IgA, and IgG antibodies can be detected successively in serum samples. IgG antibodies are generally considered as markers for any contact with the pathogen irrespective of disease stage. IgM antibodies are characteristic for acute infection and IgA antibodies indicate ongoing progression of an infection.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Sample Volume | Sample Dilution |
|--|----------|-------------------|---|--|---|
| Chlamydia pneumoniae IgA ELISA | EIA-4160 | 60/30/15 | Qualitative | Serum 10 µl /Plasma | 1:101 |
| Chlamydia pneumoniae IgG ELISA | EIA-3912 | 60/30/15 | Qualitative | Serum 10 µl /Plasma | 1:101 |
| Chlamydia pneumoniae IgM ELISA | EIA-3913 | 60/30/15 | Qualitative | Serum 10 µl /Plasma | 1:101 |
| Chlamydia trachomatis Ag ELISA | EIA-3460 | 10/60/20 | Qualitative | Urogenital/Ophthalmic Specimens (e.g. urine 25 ml) | Please have a look at the user's manual |
| Chlamydia trachomatis IgA ELISA | EIA-3461 | 60/30/15 | Qualitative | Serum/Plasma 10 µl | 1:101 |
| Chlamydia trachomatis IgG ELISA | EIA-3462 | 60/30/15 | Qualitative | Serum/Plasma 10 µl | 1:101 |
| Chlamydia trachomatis IgM ELISA | EIA-3463 | 60/30/15 | Qualitative | Serum/Plasma 10 µl | 1:101 |

Infectious Diseases ELISAS

Clostridium difficile toxin

B

Clostridium difficile is a bacterium causing nosocomial diarrhea in adults during or after the treatment with antibiotics such as 3rd generation cephalosporines. Although 2-3% of healthy adults and 20-50% of healthy children are colonized with *Clostridium difficile*, the infection is usually of exogenous origin and results from the contact either to hospital staff or to *Clostridium difficile* spores which may contaminate toilets, bed clothes etc. Both exotoxins A and B of this spore-forming bacteria cause the depolymerisation of actin filaments due to the intracellular enzymatic modification of rho-proteins. Consequently, the permeability of cell membrane is raised and neutrophils may invade leading to expression of the clinical picture of the so-called *Clostridium difficile*-associated diarrhea and colitis or finally the pseudomembranous colitis (PMC). As the production of toxins and the outbreak of disease is correlated, diagnosis of *Clostridium difficile* infection is based mainly on a direct detection of the toxins in stool specimens.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|--|----------------|--|-----------------|----------|
| Clostridium Difficile Toxin A+B Ag ELISA | EIA-4448 | 60/30/30/15 | Qualitative | | Stool/ Culture susp. 200 µl/200 mg | 1:6 | |

Corynebacterium diphtheriae toxin

B

Diphtheria is an acute communicable disease, caused by *Corynebacterium diphtheriae*. The signs and symptoms of infection are a pharyngeal membrane, sore throat, dysphasia, malaise, headache, and nausea. Death may result from respiratory obstruction by the membrane or myocarditis from the toxin.

Although diphtheria is still a serious problem in many underdeveloped countries, active immunizations in many developed countries have helped to decrease the number of reported cases of diphtheria infection. Recent epidemics in eastern Europe and Russia, combined with low levels of protective diphtheria antitoxin (DAT) in adult populations, have caused concern that outbreaks of diphtheria could occur in developed countries. A study in northern Europe reported findings of 26% of the surveyed population being below the minimum protective level of 0.01 IU/ml.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|--|----------------|----------------------|-----------------|----------|
| Corynebacterium diphtheriae toxin IgG ELISA | EIA-3466 | 10/5/5 | Quantitative | 0-2 U/ml | Serum 20 µl | 1:100 1:1000 | |
| Diphtheria IgG ELISA | EIA-2514 | 60/30/20 | Quantitative | 0-1 IU/ml | Serum/Plasma 5 µl | 1:101 | |

Coxiella burnetii

B

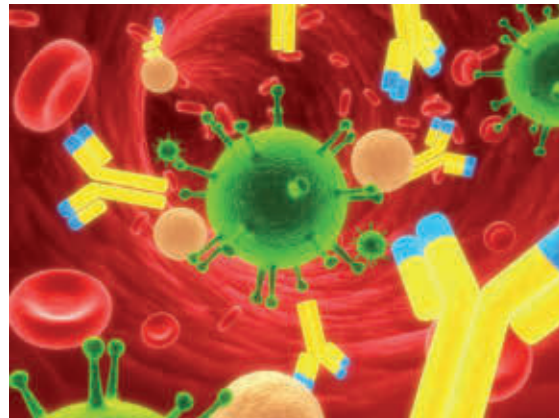
Q-Fever is a disease that results from infection with small, polymorph and gram-negative bacteria called *Coxiella burnetii*. New molecular research demonstrated a close relationship to *Legionella*. The zoonosis Q-Fever is found everywhere except New Zealand (no data available). There is an extensive reservoir (mainly ticks) of *C. burnetii*. Ticks are an important vector of the pathogen in the transmission between domestic and wildlife animals. But the ticks are unimportant in the direct infection of humans. Cattle, sheep and goats are usually the source of transmission of this microorganism to humans. However cats, dogs and rabbits are also important in this regard. In most instances humans become infected with *Coxiella burnetii* following inhalation of contaminated aerosols (respiratory tract). The acute infection shows symptoms of high fever, shivers, muscle pain and headache. Later on more severe diseases such as pneumonia or hepatitis can occur. Infections during pregnancy can lead to an abort or premature birth. Approximately 1% of all infections become chronic. The most frequent organ manifestation in Q-Fever is endocarditis. The incubation period for Q-Fever in humans is about 2 weeks. The resulting illness can be divided into acute and chronic varieties. During the acute phase of illness antibodies to the phase II-antigen are formed.

Anti phase-I antibodies in high titers are typical for a chronic disease.

Acute phase of Q-Fever: IgM specific to phase 2 after 2-3 weeks;
IgG approx. 2 months after infection

Chronic phase of Q-Fever: From 6 weeks up to 4 months after infection phase I IgG and IgA antibodies can be detected.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|--|----------------|---------------|-----------------|----------|
| Coxiella burnetii Phase I IgG ELISA | EIA-5188 | 60/30/15 | Qualitative | | 10µl Serum | 1:101 | |
| Coxiella burnetii Phase 2 IgG ELISA | EIA-5189 | 60/30/15 | Qualitative | | 10µl Serum | 1:101 | |
| Coxiella burnetii Phase I IgM ELISA | EIA-5187 | 60/30/15 | Qualitative | | 10µl Serum | 1:101 | |



Coxsackievirus

V

Coxsackievirus belongs to a group of viruses called enteroviruses in particular they are Picornaviruses. They are present in two main groups, A and B. Most Coxsackievirus infections are not serious. They typically cause only mild signs and symptoms, such as fever, rash, sore throat, joint pain and headache. Symptoms usually last about a week. Coxsackievirus infection occurs most often in young children. Group A viruses are associated with aseptic meningitis, colds, acute hemorrhagic conjunctivitis and acute myocardiopathies and group B are associated with acute myocarditis and a polio-like paralysis. Syndromes associated particularly with Coxsackie B virus are pleurodynia, also known as Bornholm disease or devil's grippé, which presents with severe pleuritic chest pain, sometimes accompanied by abdominal pain and vomiting, aseptic meningitis, colds, an myocardial or pericardial infections.

Recently immunochemical techniques have been applied to the early diagnosis of CoxB infection with ELISA tests for IgM, as a serological marker of recent infection.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|------------------------------------|----------|-------------------|--|----------------|-----------------------|-----------------|----------|
| Coxsackie B Virus IgM ELISA | EIA-5175 | 60/60/20 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Coxsackie B Virus IgG ELISA | EIA-5493 | 60/60/20 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Cryptosporidium P

Cryptosporidium is a coccidian parasite that is recognized as an important enteric pathogen. The organism causes an acute, though self-limiting infection in immuno-competent individuals. Incubation periods of 1 to 12 days have been reported with most oocyst shedding ending by day 21. Symptoms range from mild to severe diarrhea with a variety of complications. The infection in immunocompromised patients is much more severe and may often be life threatening. Passage of fluid, up to 12 liters per day, has been reported. Multiple pathways of Cryptosporidium transmission have been implicated. These include animal to human, water contamination and person-to-person. The latter may include contact between members of the same household, day care centers, and homosexual men. Diagnosis of Cryptosporidium infections was done originally by direct detection techniques. Of these, microscopic examination of stools using stains or fluorescence labeled antibodies has been the most common. However, this method relies on an experienced technician and subsequent observation of intact organisms. Because of the historically low proficiency of correct microscopic examinations, alternative diagnostic methods have been investigated. One important alternative has been the development of an antigen capture enzyme linked immuno-sorbent assay (ELISA) for use with stools. These tests, which have shown comparable sensitivity to experienced microscopic examinations, are fairly simple to perform and do not require the observation of intact organisms.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Cryptosporidium Ag ELISA | EIA-3467 | 60/30/10 | Qualitative | | Stool 1 mg | 1:4 | |

Cytomegalovirus (CMV) V

Cytomegalovirus (CMV) is a member of the herpesvirus group (Betasubfamily, DNA virus of 150-200 nm). These viruses share a characteristic ability to remain dormant within the body over a long period. Initial CMV infection, which may have few symptoms, is always followed by a prolonged, inapparent infection during which the virus resides in cells without causing detectable damage or clinical illness. Severe impairment of the body's immune system by medication or disease consistently reactivates the virus from the latent or dormant state.

CMV is found universally throughout all geographic locations and socioeconomic groups, and infects between 50% and 85% of adults.

CMV infection is more widespread in developing countries and in areas of lower socioeconomic conditions.

For the vast majority of people, CMV infection is not a serious problem, but it is to certain high-risk groups: the unborn baby during pregnancy, people who work with children, and immunocompromised persons, such as organ transplant recipients and persons infected with HIV.

The presence of virus resp. infection may be identified by Microscopy, PCR, Serology: CBR and detection of antibodies by ELISA.

IgM antibodies are the first to be produced by the body in response to a CMV infection. They are present in most individuals within a week or two after the initial exposure. IgM antibody production rises for a short time period and then declines. After several months, the level of CMV IgM antibody usually falls below detectable levels. Additional IgM antibodies are produced when latent CMV is reactivated.

IgG antibodies are produced by the body several weeks after the initial CMV infection and provide protection from primary infections. Levels of IgG rise during the active infection, then stabilize as the CMV infection resolves and the virus becomes inactive. After a person has been exposed to CMV, he or she will have some measurable amount of CMV IgG antibody in their blood for the rest of their life. CMV IgG antibody testing can be used, along with IgM testing, to help confirm the presence of a recent or previous CMV infection.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|---|----------------|--------------------|-----------------|----------|
| Cytomegalovirus (CMV) IgG ELISA | EIA-3468 | 60/30/10 | Quantitative | 10-80 DU/ml | Serum/Plasma 10 µl | 1:101 | |
| Cytomegalovirus (CMV) IgM ELISA | EIA-3469 | 60/30/10 | Quantitative | 50-400 DU/ml | Serum/Plasma 10 µl | 1:101 | |

Dengue Virus V

Dengue virus is a single-stranded RNA virus of about 50 nm in diameter belonging to the genus Flavivirus. Dengue and dengue hemorrhagic fever are caused by one of four closely related, but antigenically distinct, virus serotypes (DEN-1, DEN-2, DEN-3, and DEN-4). Infection with one of these serotypes does not provide cross-protective immunity, so persons living in a dengue-endemic area can have four dengue infections during their lifetimes. The viruses are transmitted by Aedes aegypti, a domestic, day-biting mosquito that prefers to feed on humans.

Infection with dengue viruses produces a spectrum of clinical illness ranging from a nonspecific viral syndrome to severe and fatal hemorrhagic disease.

It is primarily a disease of the tropics; its global distribution is comparable to that of malaria, and an estimated 2.5 billion people live in areas at risk for epidemic transmission.

- Globally, there are an estimated 50 to 100 million cases of dengue fever and several hundred thousand cases of dengue hemorrhagic fever.

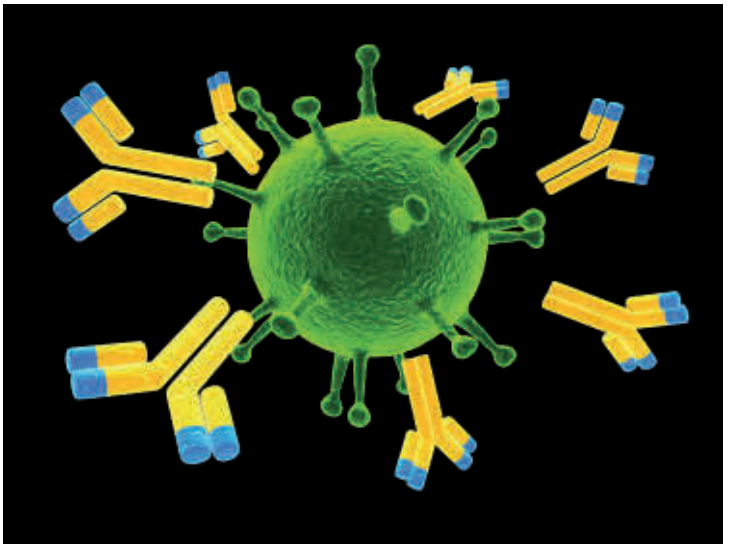
- The case-fatality rate of DHF in most countries is about 5%; most fatal cases are among children and young adults.

- Important risk factors for DHF include the strain and serotype of the infecting virus, as well as the age, immune status, and genetic predisposition of the patient.

- Risk groups: residents of or visitors to tropical urban areas.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Dengue Virus IgG ELISA | EIA-3470 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Dengue Virus IgM ELISA | EIA-3471 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |

Diphtheria see Corynebacterium diphtheriae toxin



Echinococcus P

Echinococci are microscopic cestodes (tapeworms) with a length of 1.4 to 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*)

Sources of infection are final hosts (i.e. dogs for *E. granulosus* and mainly foxes *E. multilocularis*) and food contaminated with parasite eggs.

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 where it develops into a cyst. Echinococcus infections remain silent for years before the enlarging cysts cause symptoms in the affected organs. *E. granulosus* larvae (oncospheres) begin to vesiculate mainly in the liver but also in the lungs and in other organs (20%). The parasites form spherical, unilocular, fluid-filled cysts and can achieve diameters between 1-15 cm.

In contrast to cystic echinococcosis, *E. multilocularis* larvae are found almost exclusively (98%) in the liver, but secondary lesions can spread metastatically to other organs (lungs, kidneys, CNS and others). The parasites grow infiltrative and tumor-like in the host tissue. *E. granulosus* occurs practically worldwide. *E. multilocularis* occurs in the northern hemisphere, including central Europe and the northern parts of Europe, Asia, and North America. Detectable immune responses have been associated with the location, integrity, and vitality of the larval cyst. Cysts in the liver are more likely to elicit antibody response than cysts in the lungs, and regardless of localization, antibody detection tests are least sensitive in patients with intact hyaline cysts. Cysts in the lungs, brain, and spleen are associated with lowered serodiagnostic reactivity whereas those in bone appear to more regularly stimulate detectable antibody.

Fissuration or rupture of a cyst is followed by an abrupt stimulation of antibodies.

A Differentiation between both species of *Echinococcus* is not possible.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------------|----------|-------------------|---|----------------|---------------------|-----------------|----------|
| Echinococcus IgG ELISA | EIA-3472 | 60/30/10 | Qualitative | | Serum/ 10 µl Plasma | 1:101 | |

Entamoeba histolytica P

Entamoeba histolytica is an anaerobe parasite forming cysts which have four small nuclei and measure 10-15 µm in diameter. The cysts are sturdy and resist adverse environmental conditions. After ingestion by a susceptible host (invertebrates and vertebrates including humans), its wall is disrupted by the formation of a small opening through which an amoeba emerges. The amoeba divides serially through three cycles giving rise to eight uninucleate trophozoites from one cyst which are motile and measure 20-30 µm in diameter. Some of the trophozoites then invade the tissues of the large intestine and may erode them so extensively that they gain entrance into the bloodstream. Thus, amoebae can reach all parts of the body. Infection with *Entamoeba histolytica* has worldwide distribution. It is the causative agent of amoebiasis and amoebic dysentery and inhabits the lumen and mucosa of the large intestine, predominantly the transverse colon and cecum. Extra intestinal amoebiasis can afflict any organ or tissue. The majority of infected individuals are free of symptoms; this high incidence of asymptomatic carriers complicates matters. Those who are symptomatic experience a wide range of manifestations. Members of all age groups and both sexes are infected. The risk of infection increases with inadequate sanitary conditions. An increased prevalence of amoebiasis is found among people, who have an increased risk of exposure in the agricultural occupations and in male homosexuals.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|---|----------------|--------------------|-----------------|----------|
| Entamoeba histolytica IgG ELISA | EIA-3830 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Entamoeba histolytica Ag (stool) ELISA | EIA-4454 | 60/30/10 | Qualitative | | Stool 200mg/200µl | 1:5 | |

Epstein-Barr Virus (EBV) V

Infectious mononucleosis is an acute lymphoproliferative disease that is common in children and young adults and is caused by the Epstein-Barr Virus. The EBV is one of the herpes viruses 4 (gamma).

Characteristic clinical features include:

1. fever, sore throat, and lymphadenopathy,
2. an associated absolute lymphocytosis greater than 50% containing at least 10% of atypical lymphocytes in the peripheral blood,
3. development of transient heterophil and persistent antibody responses against EBV,
4. and abnormal liver function tests.

4% of infected young adults show an icteric manifestation and 50% have splenomegaly. In addition, EBV is implicated in Burkitt lymphoma, nasopharyngeal carcinoma and Hodgkin's disease.

A syndrome similar to infectious mononucleosis can be caused by cytomegalovirus, toxoplasmosis and other viral infections. Therefore the differential diagnosis is of major importance. Serological tests like EIA are very useful for the detection of anti-EBV IgG and IgM antibodies, especially in cases where heterophil antibodies are absent. In a fresh infection IgM antibodies against VCA and EA are determined by immunofluorescence or ELISA. Later on VCA IgG appear followed by EBNA-I IgG antibodies. Correspondingly the simultaneous activation of VCA IgM and EBNA-I IgG indicates a reactivation of an EBV infection.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-----------------------------|----------|-------------------|---|----------------|---------------------|-----------------|----------|
| EBV (EA) IgA ELISA | EIA-2516 | 60/30/20 | Quantitative | 0-200 U/ml | Serum/ Plasma 5 µl | 1:101 | |
| EBV (EA) IgG ELISA | EIA-2517 | 60/30/20 | Quantitative | 0-150 U/ml | Serum/ Plasma 5 µl | 1:101 | |
| EBV (EA) IgM ELISA | EIA-2518 | 60/30/20 | Quantitative | 0-200 U/ml | Serum/ Plasma 5 µl | 1:101 | |
| EBV (VCA) IgA ELISA | EIA-2522 | 60/30/20 | Quantitative | 0.1-150 U/ml | Serum/ Plasma 10 µl | 1:101 | |
| EBV (VCA) IgG ELISA | EIA-3475 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| EBV (VCA) IgM ELISA | EIA-3476 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| EBV (EBNA) IgA ELISA | EIA-2519 | 60/30/20 | Quantitative | 1-150 U/ml | Serum 5 µl | 1:101 | |
| EBV (EBNA) IgG ELISA | EIA-4246 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| EBV (EBNA) IgM ELISA | EIA-4247 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |

E.coli

B

Invasive and toxigenic *Escherichia coli* strains cause diarrhoea in infants and adults. Among pathogenic *E. coli* strains the group of enterohaemorrhagic *E. coli* (EHEC) can cause life-threatening haemorrhagic colitis and haemolytic uraemic syndrome (HUS) leading to acute renal failure and haemolytic anaemia with thrombocytopenia. Strains like *E. coli* O:157; O:26, O:111 and other serovars are characterized by the production of cytotoxins (verotoxin 1 and 2 or shiga-toxin 1 and 2, shiga-toxin variants). The diagnosis of an EHEC infection is initially done by detection of the shiga-toxins.

Diagnostic methods can be direct toxin detection by cytotoxicity test on vero-cells and subsequent neutralization test or the detection of the encoding genes with probes or polymerase chain reaction (PCR). These methods are time-consuming and not suited for a routine diagnostic laboratory.

Immunological methods like enzyme immunoassay enable a fast and specific shiga-toxin detection in stool specimens. It is commonly recommended to enrich the EHEC bacteria in selective broth media prior to the test run to enhance the sensitivity of the method.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|---|----------------|-------------------|-----------------|----------|
| E. coli Verotoxin (stool) Ag | EIA-4204 | 30/30/10 | Qualitative | | Stool 1 g | 1:4 | |
| E. coli 0157 Ag (stool) ELISA | EIA-4229 | 30/30/10 | Qualitative | | Stool 1 g | 1:4 | |
| E. coli Verotoxin 1&2 Ag (stool) ELISA | EIA-4452 | 30/30/15 | Qualitative | | Stool 200mg/200µl | 1:2.5 | |

Fasciola

P

Fascioliasis is caused by trematodes belonging to the genus *Fasciola* (*F. hepatica* and *F. gigantica*). In the past, infection was limited to specific and typical geographical areas, but now widespread throughout the world. With human cases being increasingly reported from Europe, the Americas and Oceania (where only *F. hepatica* is transmitted) and from Africa and Asia (where the two species overlap). As a consequence, human fascioliasis should be considered as a zoonosis of major global and regional importance! Globally, the estimated number of human infections ranges from 2.4 million to 17 million. *Fasciola hepatica* causes liver rot in sheep and cattle. Snails are the first intermediate host and encystation then occurs on aquatic vegetation. Humans usually acquire infection by eating contaminated freshwater plants, but can occasionally be infected by drinking unboiled contaminated water.

Clinical aspects: Adult worms usually reside in the bile ducts, where they can live for many years, and produce eggs that pass out with bile into the feces. The early phase of migration of parasites through the liver can cause liver parenchymal destruction and be associated with fever, pain and hepatomegaly (6-12 weeks following ingestion). Diagnosis: In generally made via microscopy by identifying characteristic eggs in fecal samples or bile specimen. (However egg production does not begin until approx. 3 months after infection.)

Serological testing becomes positive during the early phase of migration through the liver and is therefore useful in diagnosing early symptoms before the appearance of eggs in the feces.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Fasciola IgG ELISA | EIA-4503 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |



Giardia lamblia

P

Giardia lamblia is one of the most common human intestinal protozoan pathogens worldwide. The incidence strongly depends on the geographic region and reaches 2-7 % in central Europe and exceeds 50 % in tropical countries.

The life cycle of *Giardia lamblia* is characterized by two stages: the trophozoite and the cyst stage. The trophozoite is the motile dividing stage and inhabits the upper small intestine. Ascending infections of the gallbladder may also occur. The cyst is the infective form of the parasite. It develops in the intestine and is excreted with the faeces. Cysts are transmitted via contaminated food or drinking water but also from persons to persons. The clinical picture of a *Giardia lamblia* infection ranges from the asymptomatic carrier state to acute diarrhea which is often accompanied by abdominal pain and flatulence. Chronic giardiasis can cause severe malabsorption syndrome. Giardiasis is usually diagnosed by microscopic detection of trophozoites and/or cysts in faecal smears after commonly used staining techniques or direct immune fluorescence. These methods are time-consuming, require trained personnel and can only detect parasites with intact morphology. Immunologic methods like enzyme immunoassays detecting *Giardia lamblia* antigens may overcome these problems.

| Product | Cat. No. | Incubation (min.) | Test principle (Qual./Quant.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|-------------------------------|----------------|----------------------|-----------------|----------|
| Giardia lamblia Ag (stool) ELISA | EIA-4453 | 30/30/10 | Qualitative | | Stool 100 mg/ 100 µl | 1:10 | |

Haemophilus influenzae

B

Haemophilus influenzae type B (HiB) is a very common cause of invasive critical infectious diseases in children up to the age of six. Following infection the symptoms of the disease include: Pericarditis, osteomyelitis, meningitis, encephalitis, pneumonia, sinusitis and otitis. In many cases the disease is lethal or leads to neurological damage, which cannot always be prevented by rapid antibiotic therapy. The underlying reason for the disease is very often a latent immunodeficiency with a specifically reduced humoral immune response to the polyribosylribitolphosphate (PRP) in the polysaccharide encapsulation of the bacterium. In children another reason is the immaturity of the immune system. Today often the term „immunocompromised patients“ is used, comprising all acquired and innate specific and unspecific immunodeficiencies. As a result, in children of 3 months of age or older a vaccination with different sorts of PRP-containing vaccines is recommended. This can lead to a clear reduction in the number of infections with *Haemophilus influenzae* type B.

The titer of antibodies produced by vaccination can be used to confirm whether the vaccination has been successful. HiB IgG ELISA is used to measure the level of PRP-specific IgG-antibodies following a 4-6 week period after complete immunization to monitor the humoral immune status of children or other individuals at risk.

| Product | Cat. No. | Incubation (min.) | Test principle (Qual./Quant.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|-------------------------------|----------------|---------------|-----------------|----------|
| Haemophilus influenzae IgG ELISA | EIA-2530 | 60/60/30 | Qualitative | 0.05-6.6 µg/ml | 20 µL | 1:26 | |

Hantavirus V

Hantaviruses (genus *Hantavirus* within the Bunyaviridae family) are enveloped negative-strand RNA viruses carried by rodents and transmitted to humans from their respective rodent reservoirs. They cause two human zoonoses, hemorrhagic fever with renal syndrome (HFRS) and hantavirus pulmonary syndrome (HPS). Soldiers, farmers and campers are particularly at risk. Hantaviruses are stable over more than 10 days at room temperature and probably remain infectious for many months. Three hantaviruses, Puumala (PUUV, carried by the bank vole), Dobrava virus (carried by the yellow-necked mouse and known also as Dobrava Af., Af. standing for *Apodemus flavicollis*) and Saaremaa (SAAV, also known in Germany as Dobrava Aa. and carried by *Apodemus agrarius*, the striped field mouse), are important in Europe.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Hantavirus (Hantaan) IgG/IgM ELISA | EIA-5237 | 45/45/10 | Qualitative | Qualitative | Serum 10 µl | 1:201 | |
| Hantavirus (Puumala) IgG/IgM ELISA | EIA-5238 | 45/45/10 | Qualitative | Qualitative | Serum 10 µl | 1:201 | |
| Hantavirus (Dobrava) IgG/IgM ELISA | EIA-5239 | 45/45/10 | Qualitative | Qualitative | Serum 10 µl | 1:201 | |

Hepatitis V

Hepatitis is inflammation of the liver. Several different viruses cause viral hepatitis. They are named the hepatitis A, B, C, D, and E viruses. All of these viruses cause acute, or short-term, viral hepatitis. The hepatitis B, C, and D viruses can also cause chronic hepatitis, in which the infection is prolonged, sometimes lifelong. Hepatitis A: is a liver disease caused by the hepatitis A virus (HAV). Hepatitis A can affect anyone. Hepatitis A can occur in situations ranging from isolated cases of disease to widespread epidemics. It is spread primarily through food or water contaminated by feces from an infected person. Rarely, it spreads through contact with infected blood. Hepatitis B: is a serious disease caused by a virus that attacks the liver. The virus, which is called hepatitis B virus (HBV), can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. Hepatitis C: is a liver disease caused by the hepatitis C virus (HCV), which is found in the blood of persons who have the disease. HCV is spread by contact with the blood of an infected person. Hepatitis D: is a liver disease caused by the hepatitis D virus (HDV), a defective virus that needs the hepatitis B virus to exist. Hepatitis D virus (HDV) is found in the blood of persons infected with the virus.

| | | | |
|-----------|---------|----------------|--|
| HAV Ab | HBs Ab | HDV Ag | Please ask for the complete panel |
| HAV IgM | HBs Ag | HDV IgM | |
| HBc Ab | HCV Ab | HEV Ab/IgG/IgM | |
| Hbc IgM | HCV IgM | HGV Ab | |
| Hbe Ab/Ag | HDV Ab | | |

Helicobacter pylori B

Helicobacter pylori is a spiral Gram-negative bacterium (2-6.5 µm in size, flagellated) which colonizes the human gastric mucosa. The organism is found in the mucus layer and adheres to the surface mucus epithelium of the stomach but generally does not penetrate the gastric mucosa directly. However, there is a secondary inflammatory response in the mucosa leading to chronic active gastritis. *Helicobacter pylori* is the primary causative agent in most cases of peptic ulcer disease. In 1994 the WHO classified *Helicobacter pylori* as a category I carcinoma. Infection rate in Europe is about 30%-40%, worldwide about 50%. There is an inverse relationship between the presence of *Helicobacter pylori* infection and socioeconomic status. In developing countries, people acquire the infection at an early age such that by young adulthood as many as 90% of the population might have *Helicobacter pylori* gastritis. In developed western countries the prevalence of *Helicobacter pylori* gastritis is much lower. Under these conditions, the rate of acquisition is much slower (roughly 1% per annum) and the older one is, the more likely one is to be infected with the organism.

| Product | Cat. No. | Incubation (Qual./Quant.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|---------------------------|---|----------------|---------------------|---|----------|
| Helicobacter pylori IgA ELISA | EIA-3483 | 60/30/15 | Qualitative/Quantitative | 0-150 DU/ml | Serum/Plasma 10 µl | 1:101 | |
| Helicobacter pylori IgG ELISA | EIA-3484 | 60/30/15 | Qualitative/Quantitative | 0-150 DU/ml | Serum /Plasma 10 µl | 1:101 | |
| Helicobacter pylori IgM ELISA | EIA-2111 | 30/30/20 | Qualitative | | Serum 5 µl | 1:40 | |
| Helicobacter pylori Ag (stool) ELISA | EIA-4354 | 120/20 | Qualitative/Quantitative | 0-1 µg/ml | Stool 100 µl/100 mg | Please have a look at the user's manual | |

Herpes Simplex Virus (HSV) V

Herpes simplex is an enveloped DNA virus (150-200 nm in diameter) belonging to the alphaherpesviridae. Based on antigenic, biochemical and biological differences it can be divided into two serotypes, HSV-1 and HSV-2. Man is the only known natural host and source of the virus. HSV-type 1 typically causes oral herpes, while HSV-type 2 typically affects the genital area. Most of the time, HSV-1 and HSV-2 are inactive, or "silent", and cause no symptoms, but some infected people have "outbreaks" of blisters and ulcers. Once infected with HSV, people remain infected for life. Herpes simplex viruses are amongst the most common infectious agents of man, and either HSV type appears to be capable of infecting similar body sites. A high percentage of the adult population is seropositive (appr. 90% HSV-1, in dependence on the socio-economic status 10-30% HSV-2). Primary HSV-1 infection usually occurs in early childhood (6 to 18 months of age). HSV-2 usually produces mild symptoms, and most people have no recognized symptoms.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------|----------|-------------------|---|----------------|--------------------|-----------------|----------|
| HSV-1 IgG ELISA | EIA-3485 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| HSV-1 IgM ELISA | EIA-3486 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| HSV-2 IgG ELISA | EIA-3487 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| HSV-2 IgM ELISA | EIA-3488 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| HSV-1 +2 IgG ELISA | EIA-3489 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| HSV-1 +2 IgM ELISA | EIA-3490 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Human Papilloma Virus



Human Papilloma Viruses are double stranded DNA organisms, without envelope, bearing to the group of Papovavirus. HPV infects epithelial cells and are associated with benign and malign lesions as papillomas, condilomas and carcinomas. Human Papilloma Viruses are pretty heterogenic and are classified in several types that include high-risk oncogenic types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) and low risk non oncogenic types.

The purified major capsidic protein L1 of HPV can self-aggregate in virus-like particles or VLPs that are morphologically and immunologically similar to the native virion. VLPs have been recently used to produce a vaccine able to protect against HPV infection in adult women whose distribution has started in many countries of the world and whose real efficacy as vaccine is under field investigation.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Human Papilloma Virus IgG ELISA | EIA-4907 | 60/60/20 | Qualitative | | Serum 10 µl | 1:100 | |

Influenza A and B



Influenza are RNA viruses of the family Orthomyxoviridae. Influenza viruses are divided into three types, designated A, B, and C which are differentiated by the specificity of a soluble antigen associated with the internal ribonucleoprotein component of the virion. The virions are spherical particles of 80-120 nm in diameter consisting of the ribonucleoprotein component and enveloped by matrix protein and a lipid bilayer which contains two spikeline structures: viral hemagglutinin (H) and viral neuraminidase (N). Influenza viruses are respiratory tract pathogens which are transmitted by direct contact, largedroplet infection, or by contaminated surfaces. Influenza types A and B are responsible for epidemics of respiratory illness that occur almost every winter and are often associated with increased rates of hospitalization and death. Type C infections usually cause either a very mild respiratory illness or no symptoms at all; it does not cause epidemics and does not have the severe public health impact that influenza types A and B do. Pandemics of influenza virus type A infections have occurred at 10 to 20 year intervals since 1890. Apparently this results from alterations in the composition of the H and N antigens (antigenic "drift" and antigenic "shift"). Currently two subtypes of Influenza A and B are circulating worldwide. Normally influenza is a self-limiting disease lasting for 3 to 7 days, but some people develop serious and potentially life-threatening medical complications, such as pneumonia, particularly in children, elderly people and other vulnerable groups.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Range) | Standard Range | Sample Volume | Sample Dilution |
|------------------------------|----------|-------------------|------------------------------------|----------------|--------------------|-----------------|
| Influenza A IgA ELISA | EIA-3792 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Influenza A IgG ELISA | EIA-3793 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Influenza A IgM ELISA | EIA-3794 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Influenza B IgA ELISA | EIA-3795 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Influenza B IgG ELISA | EIA-3796 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Influenza B IgM ELISA | EIA-3797 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |

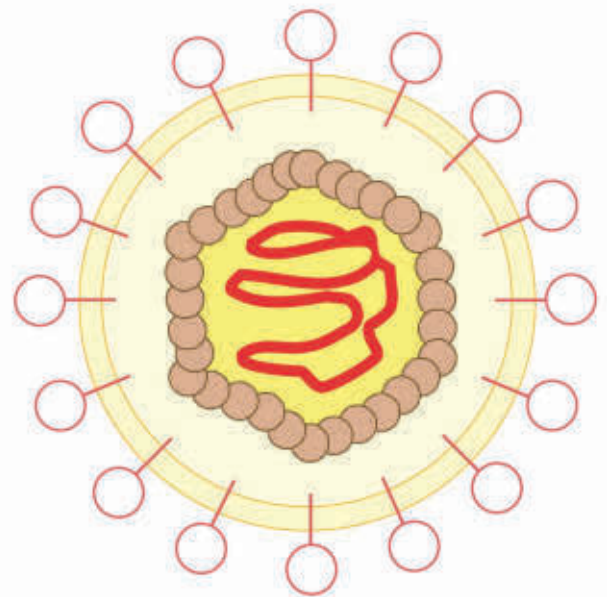
Japanese Encephalitis



Japanese encephalitis, previously known as Japanese B encephalitis to distinguish it from Economo's A encephalitis, is a disease caused by the mosquito-borne Japanese encephalitis virus. The Japanese encephalitis virus is a virus from the family Flaviviridae. Domestic pigs and wild birds (herons) are reservoirs of the virus.; transmission to humans may cause severe symptoms. Amongst the most important vectors of this disease are the mosquitoes *Culex tritaeniorhynchus* and *Culex vishnui*. This disease is most prevalent in Southeast Asia and East Asia.

Exposure to JEV causes a disease with a number of symptoms including encephalitis. The JE IgG/IgM ELISA employs a recombinant antigen called JERA, which can be used as a rapid serological marker for JEV infection. The JERA protein is a recombinant antigen, which consists of a stretch of peptides from different parts of the JE.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| JE IgG ELISA | EIA-4518 | 60/60/5/10 | Qualitative | | Serum 5 µl | 1:101 | |
| JE IgM ELISA | EIA-4505 | 60/60/60/5/10 | Qualitative | | Serum 5 µl | 1:101 | |



Legionella pneumophila (Legionnaire's Disease)

B

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. The genus *Legionella* currently has at least 50 species comprising 70 distinct serogroups. One species of *Legionella*, *L. pneumophila*, is the aetiological agent of approximately 90 % of legionellosis cases, and serogroup I (SgI) accounts for about 84 % of these cases.

L. pneumophila multiplies itself at temperatures between 25 and 42°C, with an optimal growth temperature of 35 °C. *Legionella* thrives in warm, stagnant water in the environment and in artificial systems such as cooling towers, evaporative condensers, hot and cold water systems and spa pools that mimic the natural environment in which the organism thrives. These systems also provide the means by which aerosols/droplets are generated and the organism dispersed into the atmosphere. Legionellosis can be acquired by the inhalation of aerosols containing *Legionella* bacteria or by microaspiration of ingested water contaminated with *Legionella*. Person-to-person transmission is not thought to be a risk.

The likelihood of contracting Legionnaires' disease depends on the level of contamination in the water source, the susceptibility of the person exposed, and the intensity of exposure. Legionnaires' disease is characterized as an „opportunistic“ disease that attacks individuals who have an underlying illness or a weakened immune system. Predisposing risks include increasing age, being male, heavy smoking, alcohol abuse, chronic lung disease, immunosuppressive therapy, cancer chemotherapy, organ or bone marrow transplant, and corticosteroid therapy.

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 present 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).

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution |
|---|----------|-------------------|--|----------------|--------------------|-----------------|
| Legionella pneumophila IgG ELISA | EIA-5645 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Legionella pneumophila IgM ELISA | EIA-5646 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 |
| Legionella Urinary Antigen ELISA | EIA-4205 | 30/10/5 | Qualitative | | Urine 100 µl | |

Leishmania

P

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 the macrophages they live as round, non-motile amastigotes (3-7 µm in diameter). The macrophages are ingested by the sandfly during blood-meal and the amastigotes are released into their stomach. Almost immediately the amastigotes transform into the motile, elongated (10-20µm), flagellate promastigote form, which migrate to the alimentary tract of the fly and after multiplication move forward to the salivary glands of the insect.

Leishmaniasis are a globally widespread group of parasitic diseases; the "type" is determined by the primary location of the macrophages that are infected. In humans four different forms of Leishmaniasis with a broad range of clinical manifestations are present; all can have devastating consequences. Leishmaniasis currently affects some 12 million people in 88 countries, all but 16 of which are in the developing world. It is estimated that 350 million people are exposed to the risk of infection by the different species of *Leishmania* parasite: the annual incidence of new cases is about 2 million (1-1.5 million cases of CL, 500,000 cases of VL). Visceral leishmaniasis (VL) is the most severe form of the disease, which, if untreated, has a mortality rate of almost 100%. Like many other tropical diseases, the leishmaniasis are related to economic development and man-made environmental changes, which increase exposure to the sandfly vector. The geographical distribution is limited by the distribution of the sandfly. 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.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--------------------------------------|----------|-------------------|-----------------------------|----------------|---------------|-----------------|----------|
| Leishmania infantum IgG ELISA | EIA-3843 | 60/30/15 | Qualitative | | Serum/Plasma | 1:101 | |

Leptospira

B

The clinical manifestations of leptospirosis range from a mild catarrh-like illness to icteric disease with severe liver and kidney involvement. Natural reservoirs for leptospirosis include rodents as well as a large variety of domesticated mammals. The organisms occupy the lumen of nephritic tubules in their natural host and are shed into the urine. Human infection derives from direct exposure to infected animals (veterinarians, abattoir workers, or dairy workers for example) or by exposure to environments contaminated by animal carriers (e.g. agricultural workers). Bathing or swimming in water sources about which livestock have been pastured has been demonstrated to be a potential infection hazard. The organisms enter the host through skin abrasions, mucosal surfaces or the eye. The incubation period can range from 3 to 30 days but is usually found to be 10 to 12 days. Antibodies can become detectable by the 6th to 10th day of disease and generally reach peak levels within 3 to 4 weeks. Antibody levels then gradually recede but may remain detectable for years.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-----------------------------|----------|-------------------|-----------------------------|----------------|-------------------|-----------------|----------|
| Leptospira IgG ELISA | EIA-5751 | 60/30/15 | Qualitative | | Serum/Plasma 10µl | 1:101 | |
| Leptospira IgM ELISA | EIA-5752 | 60/30/15 | Qualitative | | Serum/Plasma 10µl | 1:101 | |

Malaria

P

Malaria is one of the most common diseases in the world. More than half the world population lives in malaria-infected areas. Over 200 million cases annually result in up to 3 million deaths each year; a majority of which are in young children. In non-endemic areas, it is one of the most important imported diseases, resulting in a number of deaths in late-diagnosed or unsuspected cases each year.

The disease is caused by protozoa of the genus *Plasmodium*, transmitted by the bite of the female *Anopheles* mosquito. There are four species causing human malaria: *P. falciparum*, *P. vivax*, *P. malariae*, and *P. ovale*. The disease may also be transmitted by transfusion of infected blood. Once in the blood the sporozoite makes its way to the liver where for the next 2 weeks merozoites are produced. These are released into the blood where they invade the red cells and produce more merozoites, causing the cells to rupture. It is this rupturing that is responsible for the clinical symptoms. Of the four species, *P. falciparum* is the most common and the most virulent, causing most malaria-related deaths. *P. vivax* is the next most common cause of malaria. Although rarely fatal, this form of malaria can be accompanied by severe clinical symptoms. It is a common cause of malaria in S.E. Asia and S. America.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------|----------|-------------------|--|----------------|--------------------------|-----------------|----------|
| Malaria Ab ELISA | EIA-5511 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Malaria Ag ELISA | EIA-5411 | 60/30/15 | Qualitative | | Whole blood/Plasma 50 µl | | |

Measles Virus

V

Measles or morbilli virus belongs to the RNA viruses of the family Paramyxoviridae. The virions are spherical particles of 150-250 nm in diameter consisting of the ribonucleoprotein with helical symmetry and an envelope with spikes containing the strain-specific and hemagglutinating antigens. Morbilli viruses have no neuraminidase activity. Measles is a classic childhood disease. The virus is endemic: at the age of 20 about 90% of the population has had immunological experience with it. Newborns are protected by maternal antibodies for the first 3-4 months of life; the active disease leaves lifelong immunity. The measles virus has a contagiousness index of about 96%, is worldwide distributed, and can be serious. Bacterial superinfection was a serious threat in the preantibiotic era, but the prognosis of uncomplicated measles is now good. CNS complications such as encephalomyelitis (0.1%) which may occur after the acute phase of measles infection subsides, however still have a high mortality (10%). Prognosis of recovery in these patients is poor. Between 10-30% of all cases are fatal; 20-50% develop significant damages. Subacute sclerosing panencephalitis (SSPE) is a rare (1:1000) degenerative disease of the CNS which is thought to be a slow virus infection.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--------------------------------|----------|-------------------|-----------------------------|----------------|--------------------|-----------------|----------|
| Measles Virus IgG ELISA | EIA-3844 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Measles Virus IgM ELISA | EIA-3845 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |



Mumps Virus

Mumps viruses are RNA viruses of the family Paramyxoviridae. The virions are spherical particles of 150-250 nm in diameter consisting of a ribonucleoprotein with helical symmetry and enveloped by matrix protein and a lipid bilayer which contains two spikeline structures: viral hemagglutinin (H) and viral neuraminidase (N). Mumps virus involves primarily the parotid and related salivary glands; however infection can lead to CNS disease and accumulation of the virus in CSF. Mumps (Epidemic Parotitis) is an acute contagious viral disease mostly occurring in children. Nearly 50% of all infections are subclinical. The highest incidence of clinical manifestations is found in the age group of 4 to 15 years. Secondary infections are rare because of long-lasting immunity. 10 - 35% of mumps cases develop orchitis which occurs nearly always after puberty. The process is mostly unilateral and the prognosis usually good. Mumps virus has been one of the most important causes of viral CNS disease (meningitis and encephalitis) in USA; vaccine administration has greatly reduced its incidence.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|------------------------------|----------|-------------------|--|----------------|--------------------|-----------------|----------|
| Mumps Virus IgG ELISA | EIA-3846 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Mumps Virus IgM ELISA | EIA-3847 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Mycobacterium tuberculosis

Mycobacterioses (tuberculosis, leprosy, atypical mycobacterioses, paratuberculosis and perhaps Crohn's Disease) are the infectious diseases of men and animals with the largest diffusion on earth. The infectious agents of tuberculosis are acid-resistant rod-like formed bacteria of the family Mycobacteriaceae, genus Mycobacterium. The germ was detected by Robert Koch in 1882. Owing to the very high infectious power of pathogenic mycobacteria, early diagnosis is essential to prevent spreading of the disease. Convergences of various approaches are necessary to control the mycobacterioses, immune reactions and bacterial shedding being variable during the diseases. However, usual diagnostic procedures were up to now unsatisfying and did not allow the differentiation of mycobacterial species.

The illness is normally transferred by droplets of saliva from infected persons. The target of the infection are mostly the lungs but also other organs like the brain, intestinal tract, bones, lymph nodes and kidneys can be afflicted. Tuberculosis is not only found in developing countries with 8 million of new infections yearly but also in industrialized civilisations as an actual disease with some thousands of cases yearly. Without treatment the disease leads in 50 % of the cases to death within less than two years. Clinical symptoms are fatigue, loss of weight, lack of appetite, light fever, nocturnal sweat and pain in the chest. Especially patients with HIV are threatened by tuberculosis due to their impaired immune system.

A vaccination with living attenuated bacteria is possible (BCG = Bacille Calmette Guérin). This is mostly done with newborn or young children. With older patients, before the vaccination there is normally performed the tuberculin test (Pirquet or Mantoux) where a small amount of tuberculin is injected under the skin. In a positive case there exist antibodies against Mycobacteria and a vaccination is not necessary.

Up to recently, there have not existed any serological methods to detect tuberculosis antibodies in serum. The only available procedure was besides the skin tuberculin test the direct microscopical identification of the dyed bacteria in sputum. Meanwhile specific antigens have been prepared either by purification of natural material or by recombinant methods. In the ELISA kits for the determination of IgG / IgM / IgA antibodies a cocktail of highly pure proteins is used in order to determine an immune response against the bacteria in human serum. A fresh or chronically active infection can be diagnosed by IgA and IgM tests.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|--|----------------|-------------------|-----------------|----------|
| Tuberculosis IgA ELISA | EIA-4250 | 60/30/20 | Quantitative | 1-100 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Tuberculosis IgG ELISA | EIA-4252 | 60/30/20 | Quantitative | 1-150 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Tuberculosis IgM ELISA | EIA-4251 | 60/30/20 | Quantitative | 1-100 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Tuberculosis IgG sensitive ELISA | EIA-4508 | 60/30/20 | Quantitative | 1-150 U/ml | Serum/Plasma 5 µl | 1:101 | |

Mycoplasma hominis

Mycoplasma hominis is a strain of bacteria present in the vagina. Mycoplasma hominis is one of many organisms that may cause pelvic inflammatory disease (PID) in women. PID comprises a spectrum of inflammatory disorders of the upper genital tract among women and may include any combination of endometritis, salpingitis, tubo-ovarian abscess, and/or pelvic peritonitis. Some experts believe that Mycoplasma hominis and U. urealyticum are the causative agents of PID.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------------------|----------|-------------------|--|----------------|--------------------|-----------------|----------|
| Mycoplasma hominis IgA ELISA | EIA-5097 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Mycoplasma hominis IgG ELISA | EIA-4559 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Mycoplasma hominis IgM ELISA | EIA-4560 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Mycoplasma pneumoniae B

The mycoplasmas belong to the class Mollicutes comprising three distinct families and four genera, one of which is Mycoplasma with over 60 species. Mycoplasmas are the smallest free living organisms known (300 to 500 nm in diameter) and unlike regular bacteria they lack a cell wall. Mycoplasmas are extracellular parasites, especially on mucous membranes, which can cause infections in human, animals, plants, and cell cultures.

Mycoplasma pneumoniae is primarily a respiratory pathogen (obligat) in human involving the nasopharynx, throat, trachea, bronchi, bronchioles, and alveoli. Other Mycoplasmas, M. buccale, M. faucium, M. orale and M. salivarium are commensals in the oral cavity. Mycoplasma hominis and Ureaplasma urealyticum inhabit primarily the genital tract and may act as opportunistic invaders. M. pneumoniae is by far the most important pathogen of this group. Infection with M. pneumoniae occurs worldwide, its epidemiology has been studied primarily in the USA, Europe, and Japan. Infections are endemic in larger urban areas, and epidemic increases are observed at varying intervals. M. pneumoniae has been estimated to cause 15-20% of all pneumonias; the rate is highest in children and young adults. 74% of infections with M. pneumoniae are asymptomatic, reinfection may occur. Naturally acquired immunity to infection with M. pneumoniae appears to be of limited duration (2-3 years).

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|--|----------------|--------------------|-----------------|----------|
| Mycoplasma pneumoniae IgA ELISA | EIA-3848 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Mycoplasma pneumoniae IgG ELISA | EIA-3499 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Mycoplasma pneumoniae IgM ELISA | EIA-3500 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Norovirus V

Noroviruses belong to the family Caliciviridae, single stranded RNA viruses of 30 - 40 nm in size characterized by a typical cup-shaped capsid. Within the genus Norovirus the two human pathogenic genogroups GGI and GGII have been identified. GGI and GGII strains can be further sub-classified into at least 15 and 18 genotypes resp. The genetic heterogeneity of Noroviruses causes distinct capsid protein divergences between different genogroups (about 60%) as well as between different genotypes within one genogroup (about 20-30%). Since 1994 genotype GGII.4 is predominantly circulating. Noroviruses are very resistant to environmental conditions and highly contagious.

The infection is transmitted by direct contact to already infected people either by faecal-oral transmission or by ingestion of aerosols from vomit or by contaminated food, drinking water or objects. After a short, 10 - 50 hours lasting incubation time fulminant diarrhoea and often vomiting develop as the characteristic symptoms. The infection is usually self-limiting and symptoms disappear after 2 -3 days. Norovirus infections are characterized by seasonal fluctuations with a climax during the winter months. They are considered as the most common cause of non-bacterial gastroenteritis outbreaks worldwide, but may also be responsible for single cases of viral gastroenteritis. The high sequence variability of the capsid proteins circumvents the production of protective antibodies and hampers diagnostic detection. Methods like PCR (usually as „Real time Reverse Transcriptase PCR-Rt RT-PCR) and enzyme immunoassay are commonly used for laboratory diagnosis.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--------------------------------|----------|-------------------|--|----------------|---------------------|-----------------|----------|
| Norovirus (stool) ELISA | EIA-5694 | 60/30/10 | Qualitative | | Stool 200 µl/ 200mg | 1:6 | |

Parainfluenza 1/2/3 V

The infection with parainfluenza viruses is air-borne from man-to-man. Various species of animals may serve as virus reservoir. Parainfluenza viruses are endemically spread world-wide. The seroprevalence of parainfluenza in infants in their first year of life is 50 %. Typical for parainfluenza viruses are frequent re-infections, this applies particularly to parainfluenza 3 viruses. Incubation time is 2 - 6 days. The parainfluenza viruses are a subgroup of the paramyxoviruses. They are of the same size of approximately 150 - 300 nm. They are ether-sensitive, agglutinate human or chicken erythrocytes and have a receptor-destructive enzyme, as known from influenza viruses. They can be cultivated best in primary monkey cell cultures or in human epithelia cell cultures, however, less successful in embryonized chicken eggs. It is differentiated between parainfluenza 1, 2, 3 and 4. Together with the respiratory syncytial viruses (RSV), the pathogens belong to the major viral pathogens for diseases of the respiratory tract, accompanied by severe clinical symptoms. In adults, parainfluenza virus causes a feverish rhinitis and laryngitis. First signs are sudden headaches, pain in muscles and joints, followed by fever of 38 -39 °C. If the lower respiratory tract is involved, additionally trachyphonia and dry cough develops as a sign of tracheobronchitis. Parainfluenza-1 causes severe pneumonias in newborns, manifested by high fever, cyanosis, dyspnoea and bloody purulent sputum. Sometimes, meningitis symptoms occur at the same time. Parainfluenza-2 very often causes an acute laryngotracheobronchitis with pseudocroup in infants and children. First signs of the infection are catarrhal symptoms, followed by trachyphonia, dry barking cough and inspiratory stridor. Parainfluenza-3 viruses are considered the major pathogens of pneumonia and bronchiolitis. While types 1, 2 and 3 are distributed worldwide, parainfluenza type 4 appears only in the USA. Infections 1 and 3 occur all the year, while parainfluenza 2 and 4 viruses appear only sporadically. Laboratory diagnosis of parainfluenza viruses is done with haemagglutination inhibiting test (HIT) complement binding reaction (CF) and neutralisation test (NT). Newer methods are IFA and ELISA, which allow identification of IgG and IgA antibodies in patient serum. In differential diagnosis, tests for other paramyxoviruses like mumps, shipping fever viruses and simianvirus type 5 have to be performed due to possible cross-reactions.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--------------------------------------|----------|-------------------|--|----------------|-------------------|-----------------|----------|
| Parainfluenza 1/2/3 IgA ELISA | EIA-4351 | 60/30/20 | Qualitative/Quantitative | 1-100 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Parainfluenza 1/2/3 IgG ELISA | EIA-4349 | 60/30/20 | Qualitative/Quantitative | 1-125 U/ml | Serum/Plasma 5 µl | 1:101 | |
| Parainfluenza 1/2/3 IgM ELISA | EIA-4350 | 60/30/20 | Qualitative/Quantitative | 1-200 U/ml | Serum/Plasma 5 µl | 1:101 | |

Parvovirus B19 V

Parvoviruses are cubic single-stranded DNA viruses of about 18-32 nm lacking an envelope. Parvovirus B19 infects only humans, and since there are no crossreactivities between animal parvoviruses and B19, transmission between pets and humans is not possible. Parvovirus B19 is the causative agent of Erythema infectiosum, the so-called fifth disease, a mild rash illness that occurs most commonly in children. Infected persons are contagious during the early part of the illness before the rash appears so in adults the rate of epidemia amounts to about 60%. About 20% of adults and children who are infected with parvovirus B19 do not develop any symptoms. Persons infected with the virus, however, do develop lasting immunity that protects them against infection in the future.

Parvovirus B19 infection may cause a serious illness in persons with sickle-cell disease or similar types of chronic anemia as well as in persons who have problems with their immune system (people with leukemia or cancer, who are born with immune deficiencies, who have received an organ transplant, or who have HIV infection). Occasionally (less than 5% of all pregnant women infected with parvovirus B19) serious complications may develop during pregnancy: risk of Morbus haemolyticus fetalis.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------------|----------|-------------------|--|----------------|--------------------|-----------------|----------|
| Parvovirus B19 IgG ELISA | EIA-3503 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Parvovirus B19 IgM ELISA | EIA-3504 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Poliomyelitis Virus

V

Rickettsia conorii

B

Poliomyelitis is an infection caused by enterovirus, which occurs epidemically world-wide, and which often leads to paralysis and death. Three types of human-pathogenic poliomyelitis viruses are actually known: Type 1 (Brunhilde): often with severe symptoms, Type 2 (Lansing): with milder symptoms, Type 3 (Leon): rare, but with severe symptoms. Polioviruses mainly proliferate in the lymph nodes of the intestine, and are excreted via feces. The throat can also be infected, and the viruses then leave the body orally. After the infection, the viruses are distributed via monocytes into other lymph nodes, where they multiply. In a second viremic phase they settle in the whole organism, amongst others in the central nervous system. In more than 90% of the infections the patient does not suffer any subjective symptoms. In the remaining other cases there appear: unspecific illness with slight fever, head and throat irritations, diarrhoea, nausea, and vomiting. Very rarely the classical paralysis with affliction of muscles and cerebral nerves is seen. The reconvalescent phase can last up to two years, frequently there stay long-lasting damages. There exists no treatment of the disease, only symptomatic therapy with acetylsalicylic acid and gymnastics is possible. In many countries of the Asiatic area poliomyelitis is still endemic, but WHO has started ambitious projects to eradicate the disease. In Europe there exist cases which are imported by tourists, sometimes with lethal outcome. The diagnosis of poliomyelitis is performed by direct detection of the infectious agent in stool or throat washings during the incubation time of the virus, or by determination of antibodies in the blood. The latter is usually done by the neutralisation test, where titer differences of paired sera against the three virus types are measured separately. Only recently a Poliomyelitis IgG ELISA assay was developed in analogy to Diphtheria and Tetanus, which can detect antibodies against the three types of Polio simultaneously. This serological response can be due to a past illness or to immunity by vaccination.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--------------------------------|----------|-------------------|--|----------------|-------------------|-----------------|----------|
| Poliomyelitis IgG ELISA | EIA-2558 | 60/30/20 | Quantitative/Qualitative | 0-150 U/ml | Serum/Plasma 5 µl | 1:101 | |

Respiratory Syncytial Virus (RSV)

V

Respiratory syncytial virus (RSV) is a negative-sense, enveloped RNA virus. The virion is variable in shape and size (average diameter of between 120 and 300 nm), is unstable in the environment (surviving only a few hours on environmental surfaces), and is readily inactivated. It is the causative pathogen for the most common infection of the respiratory tract. Respiratory syncytial virus (RSV) infections usually occur during annual community outbreaks during the late fall, winter, or early spring months. The timing and severity of outbreaks in a community vary from year to year. Most infants become infected with RSV in their first winter season; between 25% and 40% have signs or symptoms of bronchiolitis or pneumonia, and 0.5% to 2% require hospitalization. Most children recover from illness in 8 to 15 days; the majority of children hospitalized for RSV infection are under 6 months of age. Most children will have serological evidence of RSV infection by 2 years of age. RSV also causes repeated infections throughout life, usually associated with moderate-to-severe cold-like symptoms; however, severe lower respiratory tract disease may occur at any age, especially among elderly or among those with compromised cardiac, pulmonary, or immune systems.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|----------------------|----------|-------------------|-----------------------------|----------------|--------------------|-----------------|----------|
| RSV IgA ELISA | EIA-3506 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| RSV IgG ELISA | EIA-3507 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| RSV IgM ELISA | EIA-3508 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Spotted Fever Group Rickettsia (SFG) are found worldwide and are generally mediated by ticks. The ensuing infection induces a specific antibody response, which may be detected and used as an indirect means of identifying an infected human. The IgM ELISA test microwells in this kit utilize the immunodominant outer membrane protein (rOmpB), which contain both species-specific and more broadly reactive determinants. Antigens used in this assay were purified from Rickettsia conorii, yet react much like antigens from Rickettsia rickettsii, Rickettsia slovaca and Rickettsia africae. The IgG EIA test microwells in this kit utilize a group-specific lipopolysaccharide (rLPS) antigen extracted from Rickettsia rickettsii, a member of the Spotted Fever Group. Other species sharing this serologic cross reactivity include Rickettsia conorii (Boutonneuse fever), Rickettsia siberica (Siberian tick typhus), Rickettsia australis (Queensland tick typhus), Rickettsia akari (Rickettsialpox) and many others.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------------------|----------|-------------------|-----------------------------|----------------|---------------|-----------------|----------|
| Rickettsia conorii IgM ELISA | EIA-4613 | 60/30/10 | Qualitative | | Serum 10 µl | 1:101 | |
| Rickettsia IgG ELISA | EIA-5297 | 60/30/10 | Qualitative | | Serum 10 µl | 1:101 | |

Rotavirus

V

Group A Rotaviruses are the most common cause of non-bacterial gastroenteritis in children aged between 4 months and 3 years. Rotavirus is excreted into the intestine in large amounts (10⁹ - 10¹¹ virus particles per g faeces). Nosocomial infections therefore cause problems especially on baby wards and in children's hospitals. Rotavirus may also be responsible for travellers diarrhea in adults and have been detected in stool specimens of asymptomatic carriers as well (1). Rotavirus is spread by faecal-oral transmission from person to person or via contaminated staff. In temperate climates Rotavirus infections are mainly observed during the winter months.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-----------------------------------|----------|-------------------|-----------------------------|----------------|---------------|-----------------|----------|
| Rotavirus Ag (stool) ELISA | EIA-3509 | 30/5/5/5 | Qualitative | | Stool 1 g | 1:5 | |

Rubella

V

Rubella is an enveloped RNA virus belonging to the togavirus. It has a spherical shape measuring about 50-70 nm in diameter. There appears to be only one antigenic type, and no cross-reactivity with alphavirus or other members of the togavirus group has been found. Rubella viruses are pathogens of the respiratory tract and transmitted mainly by droplet infection. Rubella is a worldwide common contagious disease with mild constitutional symptoms and a generalized rash. In childhood, it is an inconsequential illness, but when it occurs during pregnancy, there is a significant risk of severe damage to the fetus. The risk of congenital rubella depends primarily on the month of pregnancy in which infection is acquired: overall, approx. 16% of infants have major defects at birth following maternal rubella in the first 3 months of pregnancy. Congenital rubella infection may lead to a syndrome with single or multiple organ involvements, known as embryopathy rubellosa. In some cases infection is inapparent but results in consequential damages as eye defects, deafness, growth retardation, and others. Naturally acquired immunity usually is long-lasting, but reinfection is possible due to decreasing levels of circulating antibodies. For immunization a vaccine containing live virus is used.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual./Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--------------------------|----------|-------------------|-----------------------------|----------------|--------------------|-----------------|----------|
| Rubella IgG ELISA | EIA-3510 | 60/30/15 | Quantitative | 10-100 IU/ml | Serum/Plasma 10 µl | 1:101 | |
| Rubella IgM ELISA | EIA-3511 | 60/30/15 | Quantitative | 75-300 DU/ml | Serum/Plasma 10 µl | 1:101 | |

Schistosoma mansoni (bilharziosis) P

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. Schistosomiasis (bilharziosis) is - depending on species and location of the parasites - a disease of the intestine, liver and spleen resp. urinary passages. 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 cause 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. Not excreted eggs die after 3 weeks and will be dissolved or calcified. The affected tissue gets fibrous. In final stage bilharziosis will cause dead.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------------|----------|-------------------|---|----------------|--------------------|-----------------|----------|
| Schistosoma mansoni IgG ELISA | EIA-3872 | 60/30/15 | Qualitative | | Serum/Plasma 1:101 | 10 µl | |

Strongyloides P

Strongyloidiasis is the disease caused by the protozoan parasite Strongyloides stercoralis. This organism is an intestinal nematode with worldwide distribution, but is especially common in tropical and subtropical regions. The disease usually manifests as intestinal symptoms (mild diarrhea). In a minority of cases, the organism will become extra-intestinal and may lead to septic shock and meningitis. Serological tests are useful in detecting infection by Strongyloides if the organism goes extra-intestinal and in excluding the organism from the diagnosis of other disorders (especially hematologic malignancies). Strongyloides infected patients are particularly at risk for severe complications if they are also immunocompromised.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Strongyloides IgG ELISA | EIA-4208 | 10/5/5 | Qualitative | | Serum 5 µl | 1:64 | |

Taenia solium P

Taenia solium is a tapeworm of 2-7 m in length which resides in the small intestine of humans but also other animal species (monkeys, hamsters). The tapeworms produce proglottids (less than 1,000, and each with 50,000 eggs) which mature, become gravid, detach from the tapeworm, and migrate to the anus or are passed in the stool. The eggs contained in the gravid proglottids and passed with the faeces can survive for months to years in the environment. After ingestion of a suitable intermediate host (pigs and other animals, including humans) the eggs release the oncosphere, invade the intestinal wall and migrate to the striated muscles, into the brain, liver and other tissues of the host where they develop in cysticerci. In the human intestine, a cysticercus develops over 2 months into an adult tapeworm, which can survive for up to 25 years. The important parasitic infection caused by Taenia solium is cysticercosis which may involve the eye and the central nervous system. The swine tapeworm Taenia solium is worldwide in distribution. Prevalence is higher in poorer communities where humans live in close contact with pigs and eat undercooked pork, and is very rare in Muslim countries. The main symptom of Taeniasis (only mild) is often the passage (passive) of proglottids. The most important feature of Taeniasis solium is the risk of development of Cysticercosis.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Taenia solium IgG ELISA | EIA-3513 | 10/5/5 | Qualitative | | Serum 5 µl | 1:64 | |

Tetanus (Clostridium tetani) toxin B

Clostridia are anaerobic spore-forming gram-positive bacilli whose pathogenicity depends on the release of highly destructive enzymes or powerful exotoxins. Clostridium tetani is ubiquitous present in the soil and in the faces of various animals and produces (among others) the potent neurotoxin tetanospasmin which is released by autolysis. Hence, tetanus develop syndromes only when spores of Clostridium tetani germinate under strict anaerobic conditions after gaining access to wounds and small lacerations. Ingestion of bacteria or growth in the intestine of man or animal is without harm. Tetanospasmin is an extremely toxic agent still causing death in 50% of infected patients. In Europe tetanus mainly occurs after injuries and sometimes postoperative whereas in developing countries Tetanus neonatorum is widely disseminated causing death in up to 10% of live births. Tetanus toxin is an excellent immunogen in man - only one antigenic type of toxin. The only effective way to control tetanus is by prophylactic active immunization with formol toxoid.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|-------------------------|----------|-------------------|---|----------------|--------------------|-----------------|----------|
| Tetanus toxin IgG ELISA | EIA-3514 | 60/30/15 | Quantitative | 0.2-1 IU/ml | Serum/Plasma 10 µl | 1:101 | |

Tick-borne encephalitis (TBE) Virus V

Tick-borne encephalitis (TBE) virus is a flavivirus of the family Togaviridae. It is an enveloped single-stranded RNA virus with cubic icosahedral symmetry and ranges in size from 20-80 nm in diameter. On the European continent only two antigenic subtypes exist which show little differences in their structural proteins only. TBE virus is mainly transmitted by ticks. The degree of contamination of ticks (and thus humans) in central Europe increases from west to east, and anybody may be affected. Specific antibody development yields a life-long immunity. Tick-borne encephalitis (TBE) is the most important tick-transmitted disease of man - beside Lyme disease, which is caused by the spirochete Borrelia burgdorferi. The clinical course of disease depends on the the immune status of the infected persons. A high virus production in the primary infected tissues is required for passage of the blood-brain barrier and the resulting severe manifestations in the central nervous system.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|----------------------|----------|-------------------|---|----------------|---------------------------|-----------------|----------|
| TBE IgG (FSME) ELISA | EIA-3860 | 60/30/15 | Quantitative | 0-300 DU/ml | Serum/10 µl Citrat Plasma | 1:101 | |
| TBE IgM (FSME) ELISA | EIA-3861 | 60/30/15 | Qualitative | | Serum/10 µl Citrat Plasma | 1:101 | |



Toxocara canisP

Treponema pallidum (Syphilis)B

Toxocara canis (an ascarid) is a parasitic nematode (roundworm) commonly found in the intestine of dogs. Humans are paratenic hosts who become infected by ingesting infective eggs in contaminated soil. After ingestion, the eggs yield larvae that penetrate the intestinal wall and are carried by the circulation to a wide variety of tissues (liver, heart, lungs, brain, muscle, eyes). While the larvae do not undergo any further development in these sites, they can cause several local reactions that are the basis of toxocariasis.

In most cases, *Toxocara* infections are not serious, and many people, especially adults infected by a small number of larvae (immature worms), may not notice any symptoms. The most severe cases are rare, but are more likely to occur in young children, who often play in dirt, or eat dirt contaminated by dog stool.

The two main clinical presentations of toxocariasis are Ocular Larva Migrans (OLM), an eye disease that can cause blindness (each year more than 700 people infected with *Toxocara* experience permanent partial loss of vision), and Visceral Larva Migrans (VLM), a disease that causes swelling of ancillary body's organs or central nervous system.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------------|----------|-------------------|--|----------------|--------------------|-----------------|----------|
| Toxocara canis IgG ELISA | EIA-3865 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Toxoplasma gondiiP

Toxoplasma gondii is a small intracellular parasite, whose live cycle has a sexual and an asexual phase. Sexual development is restricted to the intestinal cells of (probably exclusively) cats; the oocysts formed are excreted and due to their resistant cell walls they may be infectious under advantageous circumstances for at least 1 year. Animals and man are intermediate hosts for the asexual proliferation of *T. gondii*: the ingested parasites will proliferate explosively within the host cells lysing them eventually. They disseminate throughout the body via circulation and lymphatic system and though may infect any cell type. In muscle and brain cells cysts are formed which are spheroidal and about 5-100 µm in diameter. Cysts are virtually immortal in the intermediate host. *Toxoplasma gondii* is the most common parasite in humans, but its abundance (7-80%) is highly dependent on the geographic area, the socioeconomic status and the nutritional customs. Infection only rarely causes toxoplasmosis and usually clinical symptoms are absent, but may produce severe problems in immunosuppressed persons and fetus. Because only a primary infection during pregnancy may be dangerous and even fatal for the unborn (the probability of congenital infection is about 50%), the recent onset of an infection must be excluded. In pregnant women in over 98% of cases, the absence of IgM excludes the possibility of recent infection. In newborns the very presence of anti-toxoplasma IgM is sufficient to confirm a congenital toxoplasmosis, since maternal IgM, unlike IgG, does not cross the placental barrier. But a significant number of infected infants do not develop detectable IgM levels and thus are false negative. In immunosuppressed patients toxoplasmosis causes severe complications mostly by reactivation of an earlier latent infection.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|--|----------------|--------------------|-----------------|----------|
| Toxoplasma gondii IgA ELISA | EIA-3683 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Toxoplasma gondii IgG ELISA | EIA-3519 | 60/30/15 | Quantitative | 50-200 IU/ml | Serum/Plasma 10 µl | 1:101 | |
| Toxoplasma gondii IgM ELISA | EIA-3520 | 60/30/15 | Quantitative | 25-100 DU/ml | Serum/Plasma 10 µl | 1:101 | |
| Toxoplasma gondii IgG Avidity Test | EIA-5066 | 60/5 | | | Serum 10 µl | 1:101 | |
| (To be used with <i>Toxoplasma gondii</i> IgG ELISA EIA- 3863 or EIA-3519) | | | | | | | |

Spirochetes are motile bacteria with a periplasmic axial filament. All pathogenic species belong to the family Treponemataceae, which includes the three genera: *Treponema*, *Borrelia*, and *Leptospira*. The *Treponema* are motile bacteria, 5-15 µm in length and 0.2 µm in width, containing about 10 flexible, undulating, spiral shaped rods. *Treponema pallidum*, the causative agent of Syphilis, is transmitted by direct contact, usually through sexual intercourse. Syphilis along with Gonorrhoea, Chancroid and Lymphogranuloma venereum designated as a venereal disease, or VD, is an acute and chronic infectious disease. After an incubation period of 12-30 days, the first symptoms to appear are chancres, soon followed by syphilitic ulcers which then spontaneously disappear in a few weeks. During this first stage (primary syphilis) the *Treponema pallidum* propagates in related lymph nodes to be distributed to the whole body stream. Three further stages of disease follow which are classified as secondary, tertiary, and quaternary syphilis.

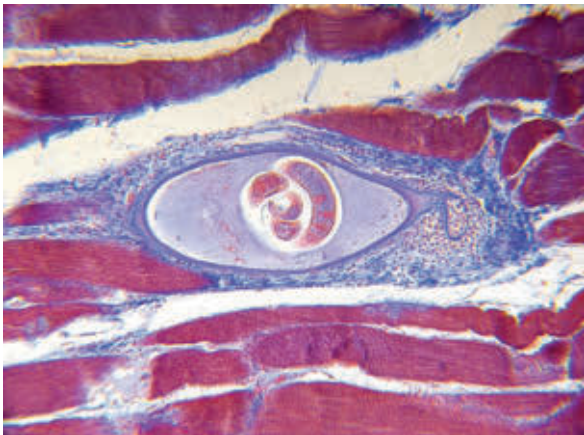
Treatment with antibiotics at the earliest disease stage and prophylactic measures are ways to prevent epidemics. For this purpose, antenatal and donor blood screenings are mandatory in most of countries around the world.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|--|----------------|---------------------|-----------------|----------|
| Treponema pallidum Screen ELISA | EIA-5549 | 60/30/15 | Qualitative | | Serum/Plasma 100 µl | | |
| Treponema pallidum IgG ELISA | EIA-3517 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |
| Treponema pallidum IgM ELISA | EIA-4267 | 60/30/15 | Qualitative | | Serum/Plasma 10 µl | 1:101 | |

Trichinella spiralisP

Trichinosis (also called trichinellosis) is caused by nematodes (roundworms) of the genus *Trichinella*. In addition to the classical agent *Trichinella spiralis*, which is found worldwide in many carnivorous and omnivorous animals, four other species (*T. pseudospiralis*, *T. nativa*, *T. nelsoni*, and *T. britovi*) are recognized. Trichinosis is acquired by ingesting meat containing cysts of *Trichinella*. After exposure to gastric acid and pepsin, the larvae are released from the cysts and invade the small bowel mucosa where they develop into adult worms (female 2.2 mm in length, males 1.2 mm). After 1 week, the females release larvae that migrate to the striated muscles where they encyst. Encystment is completed in 4 to 5 weeks and the encysted larvae may remain viable for several years. Ingestion of the encysted larvae perpetuates the cycle. Trichinosis infection occurs worldwide, but is most common in parts of Europe and the United States. Light infections may be asymptomatic. For mild to moderate infections, most symptoms subside within a few months whereas fatigue, weakness, and diarrhoea may last for months. In severe cases, death can occur.

| Product | Cat. No. | Incubation (min.) | Test principle (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---------------------------------------|----------|-------------------|--|----------------|---------------|-----------------|----------|
| Trichinella spiralis IgG ELISA | EIA-3521 | 10/5/5 | Qualitative | | Serum 5 µl | 1:64 | |



Infectious Diseases ELISAS

Trypanosoma cruzi (Chagas Disease)

P

Trypanosoma cruzi is a protozoan parasite, which is the causative agent of Chagas' disease. This disease ranges from southern United States to Northern Argentina and Chile. The disease is transmitted to humans through the bite wound caused by reduviid bugs, blood transfusions, and in newborns, infection in utero.

In acute infections, there may be few or no symptoms of the disease. In chronic infections, there may be inflammatory cardiomyopathy, or severe dilation of the esophagus or colon known as megadisease.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative): | Standard Range | Sample Volume | Sample Dilution | Specials |
|------------------------------------|----------|-------------------|--|----------------|---------------|-----------------|----------|
| Trypanosoma cruzi IgG ELISA | EIA-3464 | 10/5/5 | Qualitative | | Serum 10 µl | 1:64 | |

Tuberculosis see Mycobacterium tuberculosis

Ureaplasma urealyticum

B

Ureaplasma urealyticum is a bacterium belonging to the family Mycoplasmataceae. Its type strain is T960. This microorganism is part of the normal genital flora of both men and women. It is found in about 70% of sexually active humans. It can also cause disease, including non-specific urethritis (NSU), infertility, chorioamnionitis, stillbirth, premature birth, and, in the perinatal period, pneumonia or meningitis.

There are six recognised Ureaplasma species. They have a G+C content of 27-30 mol%, and a genome size ranging between 0.76-1.17 Gbp, and cholesterol is required for growth. A defining characteristic of the genus is that they perform urea hydrolysis. It is now recommended that some strains originally classified as Ureaplasma urealyticum should be treated as a new species, U. parvum.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|---|----------------|--------------------------|-----------------|----------|
| Ureaplasma urealyticum IgA ELISA | EIA-5098 | 60/30/15 | Qualitative | | Serum/Plasma 1:101 10 µl | | |
| Ureaplasma urealyticum IgG ELISA | EIA-4623 | 60/30/15 | Qualitative | | Serum/Plasma 1:101 10 µl | | |
| Ureaplasma urealyticum IgM ELISA | EIA-4561 | 60/30/15 | Qualitative | | Serum/Plasma 1:101 10 µl | | |

Varicella Zoster Virus

V

Varicella-Zoster Virus (human herpes virus 3, HHV-3) belongs to the α-subfamily of herpesviridae. The virus particles measure about 145 nm in diameter. They consist of doublestranded DNA, are surrounded by an icosahedral protein capsid and an envelope which contains both host cells and viral components. The virus is usually transmitted in respiratory secretions, and a single serotype causes varicella (Chickenpox), a highly infectious childhood disease, and zoster (shingles), a neurodermic disease; both diseases are found worldwide. Varicella is the acute disease which follows primary contact with the virus, whereas zoster is the response of the partially immune host to a reactivation of the varicella virus present in the body in latent form. Varicella is endemic, most commonly affected are children between 2 and 6 years of age. The course of disease is usually mild and complicated only in immunocompromised children. Rare fatal cases show multiple necrotic lesions in brain, lung (varicella pneumonia), kidneys (hemorrhagic nephritis), spleen, bone marrow, and occasionally in the intestinal tract. The lethality of varicella is below 0.1%. In the infrequent adult infections the disease is more severe, and complications are to be expected in about 5% of all cases. Zoster is of low incidence and appears with increasing frequency and severity with advancing age. Usually the process remains localized, generalization is frequently encountered in a state of immunosuppression. Fatal cases are very rare and nearly always caused by an underlying disease.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|---|----------|-------------------|---|----------------|---------------|-----------------|----------|
| Varicella zoster Virus (VZV) IgA ELISA | EIA-3522 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Varicella zoster Virus (VZV) IgG ELISA | EIA-3523 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |
| Varicella zoster Virus (VZV) IgM ELISA | EIA-3524 | 60/30/15 | Qualitative | | Serum 10 µl | 1:101 | |

West Nile Virus

V

Most people who are infected with West Nile virus (WNV) will not have any type of illness. Experts estimate that 20% of the people who become infected will develop West Nile fever: mild symptoms, including fever, headache, and body aches, occasionally with a skin rash on the trunk of the body and swollen lymph glands. Symptoms of mild disease will generally last a few days. About 1 in 150 of West Nile virus infections (<1%) result in meningitis or encephalitis. Case fatality rates among patients hospitalized during recent outbreaks have ranged from 4% to 14%. Advanced age is the most important risk factor for death, and patients older than 70 years of age are at particularly high risk. The case fatality rates for WNV are similar to St. Louis encephalitis virus and Western equine encephalitis virus (5-15%), but much lower than Eastern equine encephalitis virus (30-70%), and higher than La Crosse virus (<1%).

WNV is an arbovirus. Arboviruses are zoonotic, and are transmitted through complex life cycles involving a vertebrate (e.g., birds) and an arthropod (e.g., mosquitoes). Humans and domestic animals can develop clinical illness but usually are "dead-end" hosts because they do not produce significant viremia. So infection is most often not transmitted from person to person. Arbovirus infections can be prevented in two major ways: personal protective measures to reduce contact with mosquitoes and public health measures to reduce the population of infected mosquitoes in the environment.

WNV can be cultured, viral antigen detected, and nucleic acid can be detected in cerebrospinal fluid, tissue, blood, or other body fluid. Although a positive culture or positive results on the nucleic acid amplification test are diagnostic, low sensitivity prevents their use as routine screening tests. Viral culture of cerebrospinal fluid or brain tissue has had very low yield among U.S. patients. Nucleic acid amplification testing has been positive in up to 55% of samples of cerebrospinal fluid and 10% of serum samples. Centers for Disease Control and Prevention (CDC) recommends serology for detecting arboviruses.

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qual/Quan.) | Standard Range | Sample Volume | Sample Dilution | Specials |
|----------------------------------|----------|-------------------|----------------------------|----------------|---------------|-----------------|----------|
| West Nile Virus IgG ELISA | EIA-4519 | 60/60/5/10 | Qualitative | | Serum 5 µl | 1:300 | |
| West Nile Virus IgM ELISA | EIA-4504 | 60/60/5/10 | Qualitative | | Serum 4 µl | 1:101 | |

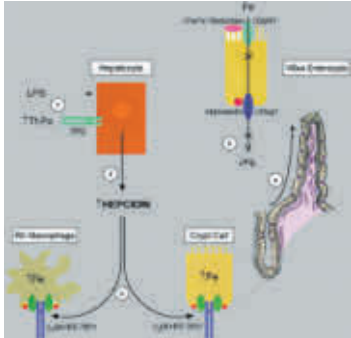
Yersinia Enterocolitica

B

The pathogenic germs Yersinia pestis, Y. pseudotuberculosis, Y. enterocolitica and Y. ruckeri belong to the genus Yersinia as a member of the enterobacteriaceae family. All the species of medical importance occur facultatively inside the cells, which leads to the characteristic inflammation of the lymphatic tissue in the course of an illness. Yersinia enterocolitica is taken up orally, and the symptoms in a patient are terminal ileitis as well as diarrhoea. It is difficult to make a separation from appendicitis by differential diagnosis. In the course of a retarded immunological reaction, extraintestinal manifestations like erythema nodosum, uveitis, and arthritis can appear. It has been claimed that the background for a reactive arthritis caused by Yersinia consists in the local synthesis of antibodies in the joints (synovial fluid).

| Product | Cat. No. | Incubation (min.) | Testprinciple (Qualitative/ Quantitative) | Standard Range | Sample Volume | Sample Dilution | Specials |
|--|----------|-------------------|---|----------------|---------------------|-----------------|----------|
| Yersinia enterocolitica IgA ELISA | EIA-2566 | 60/30/20 | Quantitative | 0.1-100 U/ml | Serum/ Plasma 10 µl | 1:101 | |
| Yersinia enterocolitica IgG ELISA | EIA-2567 | 60/30/20 | Quantitative | 0.1-100 U/ml | Serum/ Plasma 10 µl | 1:101 | |
| Yersinia enterocolitica IgM ELISA | EIA-2568 | 60/30/20 | Quantitative | 0.1-100 U/ml | Serum/ Plasma 10 µl | 1:101 | |

DRG ELISAS

| Tumormarker | Gyn. Endocrinology | Prenatal Supervision | Saliva Diagnostics |
|---|--|--|--|
| TM-CYFRA 21-I TM-CA 72-4 TM-CA 15-3 TM-CA 125 TM-CA 19-9 CEA | Estradiol Progesterone 17a-OH Progesterone DHEA-S Testosterone DHEA Estrone Androstendione DHT SHBG | PAPP-A AFP Free Estriol HCG HPL PLGF | Cortisol Estradiol Testosterone DHEA Progesterone 17a-OH Progesterone |
| Diabetes/Obesity | Iron Metabolism |  | |
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