Rapid and Reliable Antibody Detection of Parasites

RIDASCREEN® Echinococcus IgG
RIDASCREEN® Entamoeba histolytica IgG
RIDASCREEN® Leishmania Ab
RIDASCREEN® Taenia solium IgG
RIDASCREEN® Toxocara IgG
RIDASCREEN® Trichinella IgG

- Species specific detection of antibodies
- Validation for automated systems
- Parallel testing with short incubation times by ready-to-use reagents suitable for use in multiple tests
- Barcodes and user-friendly software enable fast and easy evaluation of test results
- Break-a-parts allow for single sample processing
- CE-approved

Broad range on parasite parameters

Easy and fast to perform

High sensitivity and specificity

R-Biopharm – for reliable diagnostics.

Clinical significance of parasites

Parasites are highly specialised organisms that obtain nourishment and shelter on another organism, the host. Human parasites include various protozoa and worms causing several parasitic diseases.
They are divided into endoparasites which cause infections inside the body and ectoparasites which cause infections superficially within the skin. Protozoa (such as amoebas) consist of only one cell whereas worms (helminths, such as hookworms and tapeworms) are larger, consist of many cells and have internal organs. Protozoa reproduce by cell division and therefore can reproduce inside people. In contrast, helminths produce eggs or larvae that develop in the environment before they become capable of infecting people. Development in the environment may involve another animal, an intermediate host. Some protozoa (malaria pathogen) and helminths (river blindness pathogen) are transmitted by insect vectors.
The parasites affect their hosts by direct interactions like cell invasion or adherence, by toxins and nutrition removal as well as by consequences of host-parasite-interactions in which cells and molecules of the innate and adaptive immune system and parasitic metabolites play a role. They show a high degree of specialisation and reproduce at a faster rate than their hosts. They employ numerous strategies for getting from one host to another.
There are numbers of ways in which humans can contract parasitic infections, depending on the parasite. In this context the transmission could be mediated by oral or fecal-oral uptake, by skin-penetration or injection.
The incidence of parasite infections is worldwide but there is a significant higher infection rate in tropical and sub-tropical climate zones, probably due to higher temperatures and worse hygienic conditions. It could be also shown an increased biodiversity of the parasites in these areas. In this context affected people are mainly people from developing countries as well as tourists coming from these areas. But also people with a weakened immune system show a higher infection rate.

Antigens – the Key to Success

Parasites can be detected by various methods. Many of them are time-consuming, expensive or require the release of the parasite from the host and could be therefore false-negative. Several samples and repeated examinations may be necessary to find the parasite.
Serum or blood-based test kits enable the detection of parasites even if the parasites are not released from the host (eggs, cysts, proteins etc). It is possible to differentiate species and test results are not affected by drugs as antibiotics, laxatives and antacids.
Antibody-detection test systems for parasites therefore enable a quick and beneficial diagnosis in comparison to other methods.
The choice of the antigens hereby is a key factor for the test quality.
By choosing the antigens as well as the development of the test kits R-Biopharm collaborates with international reference centers and emphasize on highest sensitivity and specificity.

R-Biopharm offers a wide range of parasite tests featuring an identical workflow for testing different parameters in parallel, therefore enabling a time and cost-effective parasite detection-method for quick and reliable results.

Worldwide prevalence of parasite infections

• Echinococcis (Echinococcus)	2 million
• Amebiasis (Entamoeba histolytica)	200 - 400 million
• Leishmaniasis (Leishmania)	12 million
• Taeniasis (Taenia solium)	60 - 70 million
• Toxocariasis (Toxocara)	350 million
• Trichinosis (Trichinella)	> 10 millions

~ 740 million infections

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Echinococcus

Parasite

- Species of tapeworms
- Infection with Echinococcus granulosus or Echinococcus multilocularis results in echinococcosis
- Disease caused by the larval stages

- **Echinococcus granulosus**
  - Adult tapeworm 4 - 7 mm long, consists of three proglottids
  - Host: mainly dogs
  - Intermediate hosts: livestock (such as sheep, deer, moose, kangaroos) and other mammals

- **Echinococcus multilocularis**
  - Small tapeworm 1.2 - 4.5 mm long, consists of 2 - 6 proglottids
  - Host: red and arctic foxes
  - Intermediate host: rodents, other small mammals and humans

Transmission

- Domestic transmission cycle
- Principally maintained in a dog-sheep-dog cycle
- Humans are accidental intermediate hosts by ingestion of eggs through direct contact with definitive hosts or indirectly through contaminated food or water
- No transmission human-to-human

Clinical picture

- Incubation time is variable (month to years)
- Asymptomatic initially for a long time
- Cysts found mostly in the liver and lungs
- Chest pain, liver enlargement
- Other organs may be affected too

Epidemiology

Global prevalence is about 2 million

- **Echinococcus granulosus**
  - Areas of occurrence: worldwide
  - Areas of high endemicity: southern South America, Mediterranean coast, southern part of the former Soviet Union, Middle East, south-western Asia, northern Africa, Australia, Kenya, New Zealand and Uganda

- **Echinococcus multilocularis**
  - Areas of occurrence: mainly on the northern hemisphere
  - Europe, Siberia, West-China and North-Japan

Performance data

RIDASCREEN® Echinococcus IgG

Inter-Assay-Variation (n=5)		Intra-Assay-Variation (n=24)	
Mean OD	CV (%)	Mean OD	CV (%)
0.223	5.7	0.099	8.6
0.592	5.5	0.357	6.9
0.840	5.0	0.840	6.3

Sensitivity: 100.0 %
Specificity: 100.0 %

Entamoeba histolytica

Parasite

- Anaerobic parasitic protozoan
- Infection with Entamoeba results in amebiasis
- Predominantly infecting humans and other mammals
- Host: humans and other mammals
- Active stage only in the host and in fresh faeces
- Cysts survive outside the host in water, soils and on food
- Cysts can be killed by heat and by freezing temperatures and survive for only a few months outside the host

Transmission

- Transmission is faecal/oral from human to human via contaminated food and water

Clinical picture

- The clinical picture is variable, mainly without symptoms
- 1 - 4 weeks after infection: stomach cramp, fever and diarrhoe with blood
- Trophozoites could invade the intestinal mucosa (intestinal disease), or, through the bloodstream, liver, brain and lungs (extraintestinal disease)

Epidemiology

- Prevalence: 200 - 400 million
- 70,000 infected persons die every year
- Spread worldwide, mostly found in countries with poor hygienic conditions;
- in industrialized countries risk groups include travellers and recent immigrants

Performance data

RIDASCREEN® Entamoeba histolytica IgG

Inter-Assay-Variation (n=5)		Intra-Assay-Variation (n=24)	
Mean OD	CV (%)	Mean OD	CV (%)
0.233	6.3	0.175	6.4
0.456	5.9	0.688	3.4
1.448	4.1	1.495	4.4

Sensitivity: 97.6 %
Specificity: 100.0 %

Publication
Eur J Clin Microbiol Infect Dis
Knappik, Börner, Jelinek
2005 Vol. 24, No. 10, 201-703
Publisher: Springer

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Leishmania

Parasite

- different species of protozoa
- Host: humans and other mammals (rodents, carnivore)
- Human infection is caused by about 21 of 30 species
- Parasitize intracellular
- Infection with Leishmania results in leishmaniasis
- One of the largest parasitic killer in the world

Transmission

- All forms of leishmaniasis are transmitted by the bite of infected nocturnal moth flies and sand flies
- Rarely, infection is spread in blood transfusions, through injections with a needle previously used by an infected person, from mother to child at birth, or through sexual contact

Clinical picture

- The clinical picture is determined by the species of leishmania as well as the immune response of the patient. People with a weakened immune system, particularly those with AIDS, are more susceptible to leishmaniasis.
- **Visceral leishmaniasis** – most serious form, affects internal organs of the body (spleen, liver and bone marrow). Symptoms typically develop gradually over weeks to months. Without treatment, 80 to 90 % of people who develop symptoms die within one to two years.
- **Cutaneous** and diffuse cutaneous leishmaniasis – most common form which causes a sore at the bite site, skin lesions
- **Mucocutaneous** leishmaniasis – begins with skin ulcers which spread causing tissue damage to nose and mouth

Epidemiology

- Areas of occurrence : worldwide
- Mostly found in tropical and sub-tropical countries, South and Central America, the Middle East, Central and West Asia, East Africa, Southern Europe
- In industrialized countries risk groups include travellers and recent immigrants
- Prevalence: 12 million

Performance data

RIDASCREEN® Leishmania Ab

Inter-Assay-Variation (n=5)		Intra-Assay-Variation (n=24)	
Mean OD	CV (%)	Mean OD	CV (%)
0.133	18.5	0.225	15.0
0.438	10.4	0.451	10.6
0.963	12.1	0.927	14.2

Sensitivity: 93.3 %
Specificity: 88.8 %

Taenia solium

Parasite

- Pork tapeworm, 2 - 7 m
- Adult tapeworms have an average of 1,000 proglottids; produce 50,000 eggs per proglottid
- Infection with Taenia could result in cysticercosis
- Host: pigs and humans
- Accidentally hosts: humans

Transmission

- Infection through contact with contaminated hands or eating infected pork

Clinical picture

- could be without symptoms
- cysticercosis: Cysticerci occur in skin, sceletal muscles, eyes and often in the central nervous system which can cause major neurological problems like epilepsy and even death

Epidemiology

- Areas of occurrence: worldwide (mostly in Asia, Africa, South America, Southern Europe, North America) in regions where humans live in close contact with pigs and eat undercooked pork, also in areas with poor hygienic conditions
- Prevalence: 60 - 70 million

Performance data

RIDASCREEN® Taenia solium IgG

Inter-Assay-Variation (n=5)		Intra-Assay-Variation (n=24)	
Mean OD	CV (%)	Mean OD	CV (%)
0.282	21.3	0.253	9.0
0.564	7.8	0.496	7.7
1.264	10.1	1.036	7.3

Sensitivity: 100.0 %
Specificity: 93.1 %

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Toxocara

Parasite

- Nematode
- Length: 9 - 18 cm long, white to yellow colour found in the intestines of the host
- Toxocara causes infections of toxocariasis
- Host: dogs
- Accidental host: humans
  The larvae do not mature to adulthood in people. They require an intermediate host for maturation: dogs, cats, or other animals

Clinical picture

- Most cases are asymptomatic, when symptoms do occur they may take two forms:
  · Visceral larva migrans (VLM), symptoms depend on the organ(s) affected: fatigue,weight loss, cramps, fever and asthma
  · Ocular larva migrans (OLM) is rare compared to VLM. Larvae enter the hosts eyes, resulting in partial or possible total blindness. Could occur year after primary infection

Transmission

- Infection mainly in young children, who acquire Toxocara eggs by ingesting soil contaminated by the feces of dogs, cats, or other animals that carry the parasite
- No direct infection animal-to-human

Epidemiology

- Worldwide, mainly in straying dogs
- nearly all puppies are infected
- 5 - 21% of all domestic dogs in Germany are infected
  Prevalence: 350 million

Performance data

RIDASCREEN® Toxocara IgG

Inter-Assay-Variation (n=5)		Intra-Assay-Variation (n=24)	
Mean OD	CV (%)	Mean OD	CV (%)
0.205	14.8	0.163	8.6
1.282	13.8	0.942	10.2
1.674	14.2	1.430	7.9

Sensitivity: 100.0 %
Specificity: 98.4 %

Trichinella spiralis

Parasite

- Genus of parasitic roundworms of Nematoda
- Length: 4.0 mm (female) and 1.5 mm (male)
- Infection with Trichinella results in trichinosis
- Two main groups are recognized in the genus:
  1. encapsulates in host muscle tissue:
     infect synapsid and mammalian hosts, larvae penetrate muscles and form cysts that can live for years in the body.
  2. non encapsulates group:
     infects saurians, crocodilians and other nonavian archosaurs and birds. Infection with this genus have been reported from more than 150 different naturally or experimentally infected hosts
- Host: mammals, mainly carnivore and omnivore, mostly spread by rodents but also pigs
- Accidental host: humans after eating improperly processed meat

Transmission

- People develop trichinosis if they eat uncooked or poorly cooked meat from an animal that carries the parasite. In most people, infections result from eating pork, particularly in regions where pigs are fed uncooked meat scraps and garbage, or eating meat from wild animals.
  No transmission from human-to-human

Clinical picture

- Symptoms vary, depending on the stage of infection, number of invading larvae, tissues invaded, and general physical condition of the person. Many people have no symptoms.
- Intestinal invasion can be accompanied by gastrointestinal symptoms (diarrhea, vomiting)
- Larval migration into muscle tissues can cause muscle pain and tenderness, weakness, fever, headache, and swelling of the face, particularly around the eyes.
- dangerous manifestations, possible leading to death are myocarditis, encephalitis, sepsis

Epidemiology

- Areas of occurrence: Worldwide in animals, most common in parts of Europe and the United States North and Middle America, Argentinia, East Africa and S/O-Asia Prevalence: >10 millions

Performance data

RIDASCREEN® Trichinella IgG

Inter-Assay-Variation (n=5)		Intra-Assay-Variation (n=24)	
Mean OD	CV (%)	Mean OD	CV (%)
0.063	16.8	0.066	13.6
0.352	12.2	0.403	9.4
1.650	4.4	1.635	10.5

Sensitivity: 94.0 %
Specificity: 99.0 %

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RIDASCREEN® ELISA for Parasite Diagnostics

- Reagents and controls are ready-to-use
- Short test procedure (3 x 15 min)
- One wash buffer (Wash) and one dilution buffer (Diluent)
- One Substrate + Chromogen and one stop reagent (Stop)
- One conjugate (Conjugate)

Sample preparation

Bring all reagents, including the microwell pouch, to room temperature (20 - 25 °C)

Dilute the wash buffer with distilled water 1:20

Dilute the serum samples with the sample buffer 1:50

Place the required number of microwell strips into the frame

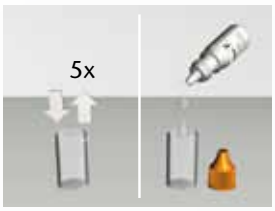
Test procedure

1.

Pipette 100 µl **Positive Control**, **Negative Control** or **Sample Suspension** into the wells

15 min Incubation at room temperature (20 - 25 °C)

2.

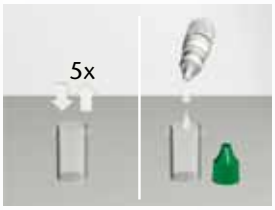


Wash 5 times with 300 µl diluted **Washing Buffer**

Add 2 drops (100 µl) of **Conjugate** in each well

15 min Incubation at room temperature (20 - 25 °C)

3.



Wash 5 times with 300 µl diluted **Washing Buffer**

Add 1 drop (50 µl) of **Substrate** and **Chromogen** in each well

15 min Incubation at room temperature (20 - 25 °C)

4.

Add 1 drop (50 µl) of **Stop-Reagent** – mix !

Photometrical measurement at 450/620 nm

R-Biopharm parasite diagnostic tests at a glance

Product	Description	Tests	Matrix	Art. No.
RIDASCREEN®	**Enzyme immunoassays for antibody detection**			
Echinococcus IgG	Enzyme immunoassay for specific detection of IgG antibodies against Echinococcus granulosus and Echinococcus multilocularis	96	Serum	K7621
Entamoeba histolytica IgG	Enzyme immunoassay for specific detection of IgG antibodies against Entamoeba histolytica	96	Serum	K1721
Leishmania Ab	Enzyme immunoassay for specific detection of IgG antibodies against Leishmania	96	Serum	K7121
Taenia solium IgG	Enzyme immunoassay for specific detection of IgG antibodies against the larval forms of Taenia solium (cysticercosis)	96	Serum	K7721
Toxocara IgG	Enzyme immunoassay for specific detection of IgG antibodies against Toxocara canis	96	Serum	K7421
Trichinella IgG	Enzyme immunoassay for specific detection of IgG antibodies against Trichinella spiralis	96	Serum	K7521

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