Anti-Plasmodium ELISA (IgG)

- **Serological determination of antibodies against all five human-pathogenic Plasmodium species**
- **Identification of latent, asymptomatic and chronic infections**
- **Reliable screening of blood and blood products**

Technical data

Antigen	Mixture of recombinant target antigens of all five human pathogenic Plasmodium species (P. falciparum, P. vivax, P. malariae, P. ovale and P. knowlesi)
Calibration	Semiquantitative: calculation of a ratio from the extinction of the sample and the extinction of the calibrator
Result interpretation	EUROIMMUN recommends interpreting results as follows: Ratio < 0.8: negative Ratio ≥ 0.8 to < 1.1: borderline Ratio ≥ 1.1: positive
Sample dilution	Serum or plasma, 1 : 101 in sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	60 min (37°C) / 30 min (37°C) / 30 min (room temperature), (sample / conjugate / substrate incubation) fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Order number	**EI 2260-9601 G**

Clinical significance

Malaria (ague, marsh fever or remittent fever) is a febrile disease caused by parasitic single-celled microorganisms of the Plasmodium genus. So far, five human pathogenic Plasmodium species have been described: Plasmodium falciparum (malaria tropica), Plasmodium vivax and ovale (malaria tertiana), Plasmodium malariae (malaria quartana) and Plasmodium knowlesi. All five human pathogenic Plasmodium species are transmitted by female mosquitoes of the Anopheles genus, which need human blood for oogenesis. Blood transfusion is another way of transmission.

The incubation time for malaria is 8 to 40 days depending on the Plasmodium species. Initial symptoms are tiredness, loss of appetite, and head and joint aches. Anaemia and splenomegaly occur and sometimes damage to the brain or gastrointestinal tract. The recurring destruction of the erythrocytes causes malarial fits, which are characterised by chills, fever and outbreaks of sweating. The frequency of fits depends on the time needed for a new generation of parasites to develop in the body. It can take one day (daily malaria, infection with two parasites at once), three days (malaria tertiana), four days (malaria quartana) or any period of time (malaria tropica). A malaria infection during pregnancy leads to anaemia, premature birth or reduced maturity of the foetus. A frequent complication in the disease course is the so-called cerebral malaria which can lead first to neurological disorders and, in a later stage, to coma. The multiple failure of inner organs can eventually lead to death of the person. P. falciparum and P vivax cause the majority of fatal malaria infections. In recent years, however, the number of severe courses of P. knowlesi infections in humans has increased.

EUROIMMUN AG · Seekamp 31 · 23560 Luebeck (Germany) · Tel +49 451 5855 0 · Fax +49 451 5855 591 · euroimmun@euroimmun.de · www.euroimmun.com

Diagnostic application

The EUROIMMUN Anti-Plasmodium ELISA (IgG) is designed for the diagnosis of Plasmodium infections and, as a supplementary test, for the exclusion of chronic courses. Therefore it plays an important role in the screening of blood donors and in epidemiology. Since in direct detection of malaria (e.g. PCR) false positive results may be obtained, depending on the time point of sample withdrawal (e.g. between fever attacks, after start of the treatment, chronic cases), serology is of major importance. The EUROIMMUN Anti-Plasmodium ELISA allows the detection of antibodies against P. falciparum, P. vivax, P. malariae, P. ovale and P. knowlesi with the highest sensitivity because it is based on specific antigens from all human pathogenic Plasmodium species.

Detection limit

The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable antibody titer. The lower detection limit of the Anti-Plasmodium ELISA (IgG) is ratio 0.04.

Reference range

The levels of the anti-Plasmodium antibodies (IgG) were analysed in a panel of 500 healthy blood donors using the EUROIMMUN ELISA. With a cut-off of ratio of 1.0, 2.0 % of the blood donors were anti-Plasmodium positive.

Reproducibility

The reproducibility was investigated by determining the intra- and inter-assay coefficients of variation using three sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on three determinations performed in ten different test runs.

	Intra-assay variation, n = 20		Inter-assay variation, n = 3 x 10	
Serum	Mean value (ratio)	CV (%)	Mean value (ratio)	CV (%)
1	2.5	2.3	2.6	3.4
2	3.5	3.2	3.5	2.4
3	5.1	3.1	5.2	3.1

Sensitivity and specificity

24 clinically precharacterised patient samples (INSTAND e.V. and Referenzinstitut für Bioanalytik (RfB), Germany) were investigated using the EUROIMMUN Anti-Plasmodium ELISA (IgG). The sensitivity was 100 %, with a specificity of 100 %. Borderline results were not included in the calculation.

n = 24		Targets from QA institutes		
		positive	borderline	negative
EUROIMMUN Anti-Plasmodium ELISA (IgG)	positive	9	1	0
	borderline	0	0	0
	negative	0	0	14

Correlation

113 serum samples (origin: Germany) from patients whose travel history suggested an investigation for malaria infection were analysed using the EUROIMMUN Anti-Plasmodium ELISA (IgG) and a competitor's test system. The qualitative results of the test systems showed an agreement of 100 % (excluding borderline sera).

n = 113		ELISA from other manufacturer		
		positive	borderline	negative
EUROIMMUN Anti-Plasmodium ELISA (IgG)	positive	8	0	0
	borderline	0	0	1
	negative	0	1	103

Literature

1. WHO – World Health Organization. WHO Malaria Report 2015, December 2015
2. Deutsche Gesellschaft für Tropenmedizin und Internationale Gesundheit (DTG, German Society for Tropical Medicine and International Health). Guideline: Diagnostik und Therapie der Malaria (Diagnosis and Therapy of Malaria). Version August 2014

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