Anti-Chikungunya Virus ELISA (IgG)

- **Specific serological test for the confirmation of chikungunya virus infections**
- **Important differential diagnosis from other symptomatically similar viral infections (e.g. dengue or Zika)**
- **Fully automatable**

Technical data

Antigen	Recombinant structural protein of chikungunya virus
Calibration	Quantitative, in relative units per milliliter (RU/ml)
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
Result interpretation	EUROIMMUN recommends interpreting results as follows: <16 RU/ml: negative ≥ 16 to < 22 RU/ml: borderline ≥ 22 RU/ml: positive Semiquantitative evaluation possible via ratio
Test procedure	60 min (37°C) / 30 min / 15 min, room temperature, 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 293a-9601 G**

Clinical significance

The chikungunya virus (CHIKV) is the pathogenic agent of chikungunya fever, an infectious tropical disease characterised by fever and joint pain. It is transmitted by mosquitoes of the genus Aedes aegypti (yellow fever mosquito) and Aedes albopictus (Asian tiger mosquito) that are active day and night. The possible transmission cycles, as well as the clinical image resemble in part the dengue fever or Zika virus infection. Chikungunya fever was first reported in 1952/1953 during an epidemic in the Makonde plateau, which is the border region between Tanzania and Mozambique, East Africa. In the Makonde language the term chikungunya stands for "crookedly walking patient" due to its main symptom of severe joint and muscle pains accompanied by a high sensitivity to touch in the whole body (70% to 99% of cases). In addition to the generally rapidly rising high fever (38.5 to 40 °C), chikungunya virus infections are characterised by lymph node swelling, maculo-papulous rash with little or moderate itching (approx. 50%), rarely occurring punctual bleeding of the skin (petechia), milder forms of mucosa bleeding, e.g. of the nose or gums (approx. 25%), headache, fatigue and ophthalmitis.

Diagnostic application

The Anti-Chikungunya virus ELISA (IgG and IgM) is of great importance for the serological detection of acute or past chikungunya infections and is also a supplement to the direct detection of the pathogen, e.g. using RT-PCR. Seroconversion or a significant increase in the IgG antibody titer of at least 4 fold indicates an acute infection. Alongside diagnosis of the disease, serology can also be applied to gather epidemiological data and for blood bank screening.

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Reference range

The levels of anti-chikungunya virus antibodies (IgG) were analysed with the EUROIMMUN ELISA in a panel of 498 healthy blood donors. With a cut-off value of 20 RU/ml, 2.0% of the blood donors were anti-chikungunya virus positive (IgG).

Reproducibility

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

	Intra-assay variation, n = 20		Inter-assay variation, n = 4 x 6	
Sample	Mean value (RU/ml)	CV (%)	Mean value (RU/ml)	CV (%)
1	22	9.7	24	9.1
2	37	7.1	36	7.1
3	95	8.1	101	6.0

Neutralisation test

The sensitivity was determined by investigating 143 pre-characterised patient samples (reference method: plaque reduction neutralisation test) with the EUROIMMUN Anti-Chikungunya Virus ELISA (IgG). The sensitivity was 98.6%. Borderline results were not included in the calculation.

n = 143		Neutralisation test	
		positive	negative
EUROIMMUN Anti-Chikungunya Virus ELISA (IgG)	positive	138	2
	borderline	0	1
	negative	2	0

Specificity and sensitivity

Study I: 352 precharacterised samples of different origins were investigated with the EUROIMMUN Anti-Chikungunya Virus ELISA (IgG). The sensitivity was 96.8%, with a specificity of 98%. Borderline results were not included in the calculation.

n = 352		Precharacterisation	
		positive	negative
EUROIMMUN Anti-Chikungunya Virus ELISA (IgG)	positive	241	2
	borderline	2	2
	negative	8	97

Study II: 219 precharacterised patient samples (origin: Europe; reference method: EUROIMMUN Anti-Chikungunya Virus IIFT (IgG)) were investigated with the EUROIMMUN Anti-Chikungunya Virus ELISA (IgG). The sensitivity was 95.8%, with a specificity of 98%. Borderline results were not included in the calculation.

n = 219		EUROIMMUN Anti-Chikungunya IIFT (IgG)	
		positive	negative
EUROIMMUN Anti-Chikungunya Virus ELISA (IgG)	positive	113	2
	borderline	0	2
	negative	5	97

Cross reactivity

The quality of the antigen used ensures a high specificity of the ELISA. Sera from patients with infections caused by various agents were investigated with the Anti-Chikungunya Virus ELISA (IgG). It needs to be taken into consideration that strong cross-reactions within the Alphavirus genus cannot be ruled out. However, it must also be taken into account that double infections, particularly in endemic areas, or infections with another alphavirus at an earlier time are possible. In this case, positive results are not caused by a cross-reactivity of the corresponding antibodies.

Antibodies against	n	Anti-Chikungunya Virus ELISA (IgG) positive
Barmah Forest virus	46	2.2%
Mayaro virus	2	50%
Ross River virus	60	30%

Literature

1. Prat CM, et al. **Evaluation of Commercially Available Serologic Diagnostic Tests for Chikungunya Virus, Emerg Infect Dis**. 2014;20(12):2129-2132.
2. De Salazar PM, et al. **Evaluation of three commercially-available chikungunya virus immunoglobulin G immunoassays, Rev Panam Salud Publica.** 2017; 41:e62

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EI_293a_D_UK_A04, 06/2019