Anti-Hepatitis E Virus (HEV) ELISA Camel (IgG)

- **Sensitive antibody detection to support the diagnosis of infections with hepatitis E virus in camels**
- **Recombinant structural protein as the antigen for specific determination of anti-HEV antibodies**
- **Efficient automation solutions available**

Technical data

Antigen	Recombinant ORF2 antigen of the hepatitis E virus genotype 7
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	Camelid serum or plasma, 1:101 in sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions
Test procedure	30 min (37 °C) / 30 min (37 °C) / 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 2525-9601 GK**

Clinical significance

Hepatitis E virus (HEV) belongs to the *Hepeviridae* family and is one of the most frequent causes of acute viral hepatitis in humans worldwide. Epidemic HEV infections often occur in developing countries. However, the number of sporadic cases is also increasing in industrialised countries. While HEV infection in humans is generally self-limiting, pregnant women and infants in developing countries show an increased fatality rate. Immunocompromised patients may develop a chronic HEV infection. Infection generally occurs via contaminated food, for instance, by consumption of contaminated water or raw or insufficiently heated meat or milk from infected animals. Transmission via direct contact with infected animals cannot be ruled out. There are different genotypes of the virus, some of which have zoonotic potential and can infect other mammals besides humans, e.g. pigs. The mostly subclinically infected reservoir animals are a risk for humans. A novel hepatitis E virus has been isolated in dromedaries. The so-called camel-associated HEV, classified as genotype 7 (HEV-G7), has already been detected in humans. For this reason, dromedaries are discussed as a reservoir of HEV. Especially camel calves are often infected with HEV-G7 and represent a potential infection source for persons before neutralising antibodies have been produced. HEV-infected camels rarely develop clinical symptoms. The most reliable laboratory diagnostic methods for confirmation of suspected HEV infections in camels include the direct detection of HEV using PCR and the detection of antibodies against HEV using indirect immunofluorescence (IIFT), ELISA or neutralisation tests. The use of a specific recombinant structural protein of the camel-associated HEV-G7 as the antigen in the ELISA enables sensitive detection of HEV-specific antibodies in camels. Positive results should be confirmed with another method, ideally by means of a neutralisation test.

Test principle

The test kit contains microplate strips each with 8 break-off reagent wells coated with recombinant antigens of hepatitis E virus. In the first reaction step, diluted patient samples are incubated in the wells. In the case of positive samples, the specific IgG antibodies (also IgA and IgM) will bind to the corresponding antigenic site. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled anti-camel IgG (enzyme conjugate), which is capable of promoting a colour reaction.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation (CV) 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 (ratio)	CV (%)	Mean value (ratio)	CV (%)
1	0.7	8.8	0.6	13.3
2	1.9	3.1	1.9	6.7
3	6.3	3.0	6.3	5.1

Sensitivity and specificity

The sensitivity of the test was determined by investigating sera from five camel calves. For each animal, two samples were investigated using the EUROIMMUN Anti-Hepatitis E Virus (HEV) ELISA Camel (IgG): one sample taken approx. one month prior to a positive PCR results, and one samples taken five to seven months after the positive PCR result (see table). The specificity was determined by analysing 19 camelid sera from German zoos with a negative expected value. The sensitivity and specificity of the Anti-Hepatitis E Virus (HEV) ELISA Camel (IgG) were 100%.

Camel	**Anti-Hepatitis E Virus (HEV) ELISA Camel (IgG)**	
	Sample collected before pos. PCR	Sample collected after positive PCR
1	negative	positive
2	negative	positive
3	negative	positive
4	negative	positive
5	negative	positive

More data can be found in the publication by Corman et al., 2020, indicated below.

Literature

1. Corman VM, et al. **Hepatitis E virus genotype 7 shedding and antibody kinetics in naturally infected dromedary calves, United Arab Emirates.** Emerg Infect Dis 20 (2020) 276-279.
2. Rasche A, et al. **Hepatitis E Virus Infection in Dromedaries, North and East Africa, United 53 Arab Emirates, and Pakistan, 1983-2015.** Emerg Infect Dis 22 (7) 2762016.
3. Sridhar S, et al. **Hepatitis E Virus Genotypes and Evolution: Emergence of Camel Hepatitis E Variants.** Int J Mol Sci 18(4):869 (2017).
4. Woo PCY, et al. **New hepatitis E virus genotype in camels, the Middle East.** Emerg Infect Dis 20(6):1044-1048 (2014).