LKM1 ELISA

Type 2 Autoimmune Hepatitis: Determination of Liver-Kidney Microsomes-1 Autoantibodies

Simple
Microwell Enzyme-based assay (ELISA)
Rapid turnaround
Room temperature incubation

Convenient
Ready to use reagents
Controls provided

BIOMERICA

CE and EN ISO 13485 compliant

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INTENDED USE

The Biomerica LKM1 ELISA is intended for the quantitative detection of autoantibodies to Liver-Kidney Microsomes Type-1 in human Serum. This assay is intended for *in vitro* diagnostic use only.

BACKGROUND

Autoimmune hepatitis (AIH) is a chronic progressive liver disease of unknown origin. After exclusion of alcoholic, drug-induced or viral liver disease, a diagnosis of AIH can be established based on epidemiological, histological and biological findings and on a positive response to immunosuppressive therapy (1,2). Several autoantibodies can be observed in AIH and, although it is not recommended to subdivide patients with AIH based on their autoantibody profile, it is commonly admitted that type 1 autoimmune hepatitis is associated with various anti-nuclear antibodies (ANA) and/or with anti-smooth muscle antibodies (ASMA) reacting with actin cables (3,4). In contrast, type 2 AIH is characterised by the absence of ANA and ASMA and the presence of antibodies to liver/kidney microsome type 1 (anti-LKM1) and liver cytosol type 1 (anti-LC1). Other autoimmune markers, such as anti-soluble liver antigen /liver pancreas (anti-SLA/LP) have been proposed (5,6) in the putative type 3 AIH.

Three type of anti-LKM autoantibodies have been characterized, the serological marker for type 2 AIH being the LKM type 1 autoantibody first described in 1973 by Rizetto using the immunofluorescence method on rodent liver and kidney sections (7).

Most patients will enter into remission but relapse after withdrawal of therapy occurs in 60 to 80% of children (12) and is also common in adults. Although it appears that the concentration of anti-LKM1 antibodies parallels changes in disease activity and is well correlated to γ-globulin levels (11), the current consensus is to use histological findings or other biological indicators (aminotransferase, bilirubin) to assess a state of remission (2). Therefore, the main clinical application of anti-LKM1 testing remains, together with ANA and ASMA testing, the frontline laboratory work up of chronic or acute hepatitis of unknown cause (13).

Low concentrations of anti-LKM1 autoantibodies can be found in patients with hepatitis C. In Europe, it has been shown that these antibodies react to different epitopes on the recombinant CYP2D6 molecules, compared to antibodies found in type 2 AIH (14) From an epidemiological standpoint, these patients are quite different from the type 2 AIH group : they are older, predominantly male and with true HCV infection. Screening for ANA, ASMA and anti-LKM1 in HCV patients is now recommended before initiating interferonalpha therapy. While immunosuppressive therapy for AIH is harmful, interferons may exacerbate the overlapping autoimmune hepatitis (15, 16).

PERFORMANCE

Sensitivity - Minimum detectable dose: 0.2 U/ml

Precision

r = 12	Sample 1	Sample 2	Sample 3
Mean concentration (U/ml)	5.7	47	51
Standard deviation (U/ml)	0.5	3.7	3.7
Coefficient of variation (%)	8.5	7.8	7.2

Reproducibility

r = 5	Sample 1	Sample 2	Sample 3
Mean concentration (U/ml)	5	12	29
Standard deviation (U/ml)	0.9	1.3	3.2
Coefficient of variation (%)	18	10	11

ORDERING

Catalog No.	Description
7052	LKM1 ELISA kit - Quantitative (96 tests)

CE and EN ISO 13485:2003 Compliant, Multi-language inserts available

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