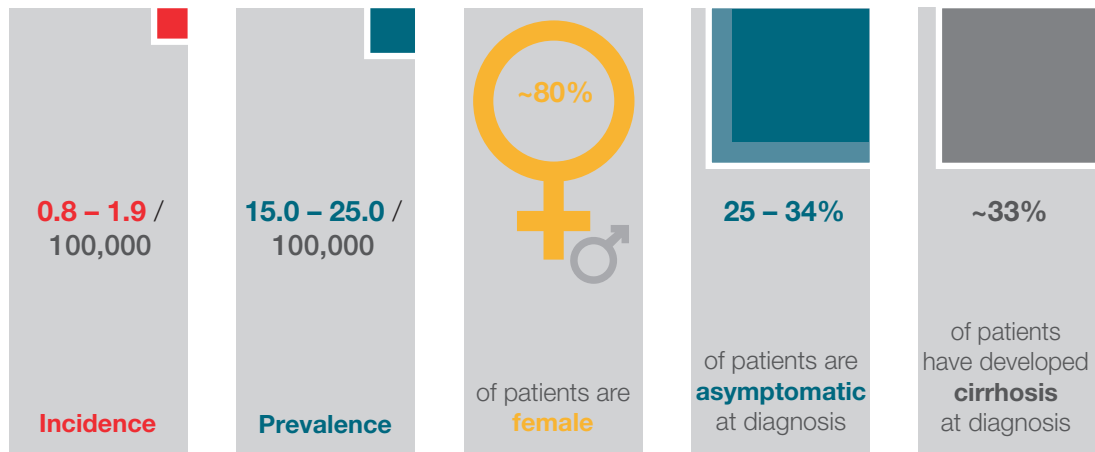# Flexible and automated testing for AIH type 2

EliA LKM-1 test

Autoimmune hepatitis (AIH)

Inflammation and apoptosis of hepatocytes leading to liver failure[1-3]

0.8 – 1.9 / 100,000	**15.0 – 25.0** / 100,000	**~80%** of patients are **female**	**25 – 34%** of patients are **asymptomatic** at diagnosis	**~33%** of patients have developed **cirrhosis** at diagnosis
Incidence	**Prevalence**			

AIH subtypes and clinical implications

AIH type 1
approx. 90% of AIH patients[1-3]

- Onset at any age

- Variable disease severity

- Rare failure of treatment

- Variable relapse rates after drug withdrawal

- Presence of ANA, ASMA and/or anti-SLA/LP

AIH type 2
approx. 10% of AIH patients[1-3]

- Usually affects children and young adults

- Clinically more severe

- Frequent failure of treatment

- Frequent relapse after drug withdrawal

- Presence of anti-LKM-1 and/or anti-LC1

Identifying patients with autoimmune hepatitis type 2 enables the clinician to improve patients' quality of life

thermo scientific

Testing for anti-LKM 1 antibodies

Anti-LKM-1 antibodies[1,2]

- Often measured by time-consuming immunofluorescence assays (IFA)[1]

- Interpretation of IFA patterns requires experienced staff[1]

- Based on the molecular characterization of the LKM-1 antigen as cytochrome P450 2D6, the results of anti-LKM-1 IFA and enzyme immunoassays (EIA) are considered interchangeable[1]

EliA™ LKM-1 test – key features[4]

Antigen: recombinant human LKM-1 manufactured in-house

Controls: EliA™ AIH Positive Control and EliA™ IgG/IgM/IgA Negative Control

Automation: available for Phadia™ 200, Phadia™ 250 and Phadia™ 2500/5000 instruments

Flexibility: random access* testing with ready-to-use reagents to adjust to varying testing needs

Efficiency: easy add-on to EliA test portfolio by using the EliA IgG calibration method

Cost savings: interchangeable reagents with other EliA tests, e.g. EliA™ M2 test and EliA™ CTD Screen[5,6]

*random access testing available on Phadia 250 and Phadia 2500/5000 instruments

Clinical performance of EliA LKM-1 test[7]

	Sensitivity [%]	Specificity [%]	PPV [%]	LR (+)
EliA LKM-1 test	67.9	96.5	90.2	19.6
IFA (cut-off 1:40)	69.1	94.8	86.2	13.3
At stratified specificity of 94.8%				
EliA LKM-1 test	72.8	94.8	86.8	14.0
IFA	69.1	94.8	86.2	13.3

PPV: Positive predictive value   LR(+): Positive likelihood ratio

Table 1:
Study cohort: 81 AIH type 2 patients and 173 disease controls (including AIH type 1, primary biliary cholangitis, primary sclerosing cholangitis, hepatitis C virus). Receiver Operating Curves (ROC) data was used to compare sensitivities at a defined (stratified) specificity.

- EliA LKM-1 test and IFA had a similar clinical performance

- Compared to IFA, EliA LKM-1 test had fewer false positive test results leading to higher PPV and LR(+)

- At the stratified specificity of 94.8%, EliA LKM-1 test had a higher sensitivity than IFA

Technical data[4]

Ordering information	Article No.	Package size	Cut-off negative	Cut-off equivocal	Cut-off positive	Short name
EliA LKM-1 Well	14-6648-01	2 x 16 wells	< 7 U/ml	7-10 U/ml	> 10 U/ml	lkm

References

1. European Association for the Study of the L. EASL Clinical Practice Guidelines: Autoimmune hepatitis. *J Hepatol*. 2015;63(4):971-1004.
2. Czaja AJ. Diagnosis and Management of Autoimmune Hepatitis: Current Status and Future Directions. *Gut Liver*. 2016;10(2):177-203.
3. Francque S, Vonghia L, Ramon A, Michielsen P. Epidemiology and treatment of autoimmune hepatitis. *Hepat Med*. 2012;4:1-10.
4. Directions for Use, EliA LKM-1 250-6648-020 / UK
5. Directions for Use, EliA M2 250-5649-021 / UK
6. Directions for Use, EliA CTD Screen 250-5596-022 / UK
7. Thermo Fisher Scientific. Internal study.

Thermo Fisher
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