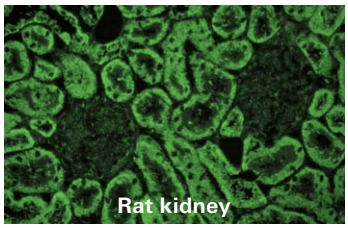
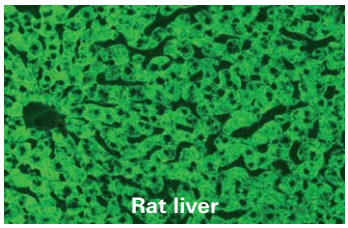
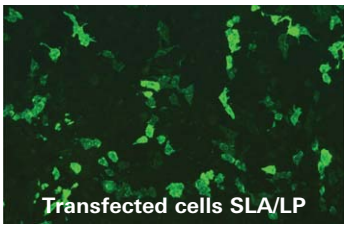
IIFT: BIOCHIP Mosaic Liver Screen 1







- **BIOCHIP Mosaic consisting of four substrates for the detection of antibodies relevant in the differential diagnosis of autoimmune liver diseases**
- **Contains a recombinant cell line for monospecific detection of autoantibodies against soluble liver/pancreas antigen (SLA/LP)**

Technical data

Antigen substrate	Tissue sections of rat kidney, rat liver, rat stomach and transfected cells (EU 90)
Sample material	Serum or plasma
Sample dilution	Qualitative evaluation: 1:100; quantitative evaluation: from 1:100/1000/10000 etc.
Reagents	Ready for use, with the exception of the PBS Tween buffer
Test procedure	30 min (sample) / 30 min (conjugate), room temperature
Microscopy	Objective: 20x; light source: EUROIMMUN LED, EUROStar Bluelight or mercury vapour lamp, 100 W; excitation filter: 450-490 nm, colour separator: 510 nm, blocking filter: 515 nm
Stability	18 months from the date of manufacture when stored at +2 °C to +8 °C
Test kit format	10 slides, each containing 5 or 10 test fields
Order no.	**FA 1300-####-21**
Related products	FA 1302-####-50 Anti-Soluble Liver Antigen/Liver-Pancreas Antigen (SLA/LP) IIFT

Clinical significance

The determination of numerous autoantibodies against liver-specific and systemic antigens is crucial for the diagnosis of autoimmune liver diseases (AiLD). A number of test procedures have become established for this application, for example IIFT, blot and ELISA. In particular, multiparameter profiles such as IIFT Mosaics and line blots (EUROLINE) are recommended. To obtain a secure diagnosis of AiLD it is absolutely essential to exclude viral hepatitides (A-E), hepatitides accompanying other infections, toxic hepatitides as well as metabolic and hereditary liver diseases.

AiLD encompass the following diseases: autoimmune hepatitis (AIH), primary biliary cirrhosis (PBC) and primary sclerosing cholangitis (PSC). The following autoantibodies are associated with AIH: anti-nuclear antibodies (ANA), nDNA, smooth muscles (ASMA), liver-kidney microsomes (LKM-1), cytosolic liver antigen type 1 (LC-1) and SLA/LP. The autoantibodies against SLA/LP that can today be measured by various EUROIMMUN enzyme immunoassays probably have the highest diagnostic accuracy of all antibodies involved in AIH. Their prevalence is only between 10 and 30 %, but the predictive value is almost 100 %.

PBC is an immunomediated, chronic-inflammatory, cholestatic liver disease of unknown cause. The serological detection of antimitochondrial antibodies (AMA) is particularly important in diagnostics because both the clinical picture and imaging procedures do not allow reliable diagnosis of PBC. AMA can be detected by IIFT using different (histological) substrates, with tissue sections of rat kidney being the standard substrate. With the AMA IIFT, autoantibodies against AMA as a reliable indicator of PBC can be successfully determined with high specificity and sensitivity. Besides AMA, ANA may also be found by IIFT in about one third of patients with PBC.

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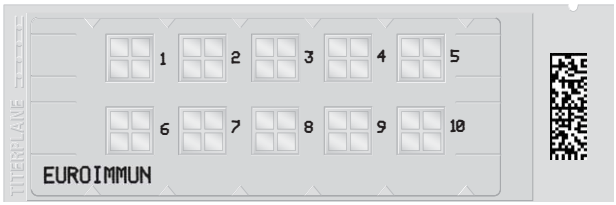
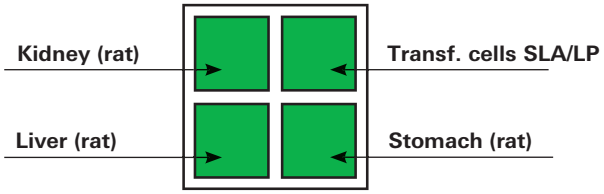
Diagnostic application

Antibodies against AMA, ASMA, LKM, SLA/LP and ANA are highly relevant in the diagnosis of AIH and PBC. The combination of the IIFT substrates kidney, liver and stomach allows simultaneous investigation of relevant antibodies – except for SLA/LP. The SLA/LP-transfected cells provided in the Mosaic fill in this gap and enable diagnosis through antibody screening.

BIOCHIP arrangement

The IIFT product Liver Screen 1 is available in two formats: slides with five or ten application areas. One test field contains four BIOCHIPs.





Reference range

Titer 1: < 100

Specificity and sensitivity

Substrate	Ig class	Origin of samples	Reference (number of samples)	Specificity	Sensitivity
Liver (rat): anti-LKM	IgG	Germany	Reference centres (n = 30)	100 %	100 %
Liver (rat): ANA	IgG	Germany	IIFT (HEp-2) (n = 200)	100 %	–
Liver (rat): ANA	IgG	Germany	IIFT (HEp-2) (n = 37)	–	59 %
Kidney (rat): AMA	IgG IgAGM IgG	Germany	Reference centres (n = 33) Reference centres (n = 38) AMA-M2 ELISA (n = 103)	100 % 100 % 100 %	100 % 100 % 98 %
Kidney (rat): anti-LKM	IgG IgAGM	Germany	Reference centres (n = 32) Reference centres (n = 37)	100 %	100 %
Stomach (rat): ASMA	IgG IgAGM	Germany	Reference centres (n = 31)	100 %	100 %

Antibodies Substrate	Ig class	Origin of samples	Sample characterisation Clinical patient panels	n	Prevalence	
					positive	%
Anti-SLA/LP Transfected cells	IgG	Germany, USA Greece, Poland	Patient samples with positive serological precharacterisation using the Anti-SLA/LP ELISA or Liver Profile EUROLINE*	50	50	100 %
	IgG	Italy	Samples from patients with autoimmune hepatitis type I	61	10	16.4 %
	IgG	Germany	Patient samples with negative serological precharacterisation using the Anti-SLA/LP ELISA or Liver Profile EUROLINE*	45	0	0 %
	IgG	Italy, Germany	Samples from patients with with autoimmune liver diseases (PBC, coeliac disease, PSC) or infection-induced liver diseases (hepatitis B, hepatitis C), healthy blood donors	235	1	0.4 %

* Precharacterisation with Anti-SLA/LP ELISA and EUROIMMUN Liver Profile EUROLINE (AMA-M2, LKM-1, LC-1, SLA/LP)

Literature

1. Bogdanos DP, et al. **Autoimmune liver serology: current diagnostic and clinical challenges.** World J Gastroenterol. 2008 Jun 7;14(21):3374-87. Review
2. Hennes EM, et al. International Autoimmune Hepatitis Group. **Simplified criteria for the diagnosis of autoimmune hepatitis.** Hepatology. 2008 Jul;48(1):169-76

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