Clinical Performance Report: Microblot-Array Liver profile

(Abbreviated Version)

The Microblot-Array Liver Profile IgG assay was evaluated in an external clinical performance study at the independent specialized laboratory the Instituto of Rheumatology (Prague, Czech Republic), in compliance with IVDR requirements.

The study aimed to generate objective, reliable performance data under real clinical conditions.

Monitored performance characteristics

- Diagnostic sensitivity and specificity
- Positive and negative predictive value
- Likelihood ratios of the kit for positive and negative test
- Comparison with a reference method

Samples

- Anonymized, archived residual samples from routine clinical testing, sourced from a general population indicated for IgG antibody testing for autoimmune disease diagnostics.
- Healthy blood donor samples
- Commercially available samples (ensuring reliability and representativeness of sample set)

Table 1: Tested samples

	Panel of positive samples		**Panel of negative samples**	
	Primary biliary cholangitis	**Autoimmune hepatitis**	**Infectious hepatitis**	**Healthy donors**
Number of tested samples (n = 123)	44	19	30	30
Population	General (Individuals of all ages and ethnicities)			
Sample source	Residual from routine, comercial[2]			
Date of sample collection	2023-2024		05-10/2024	

[2] Primary Biliary Cirrhosis Serum, Human, NIBSC code: 67/183; CDC Multiple Nuclear Dots antibody Reference Material for ICAP Pattern AC-6, Cat. No: IS2728; CDC Anti-Mitochondrial Antibody (AMA) Reference Material for ICAP Pattern AC-21, Cat. No: IS2724

Reference method for clinical performance comparison

Reference methods like the Microblot-Array Liver Profile IgG are immunoenzymatic tests for determination of IgG antibodies against Liver antigens

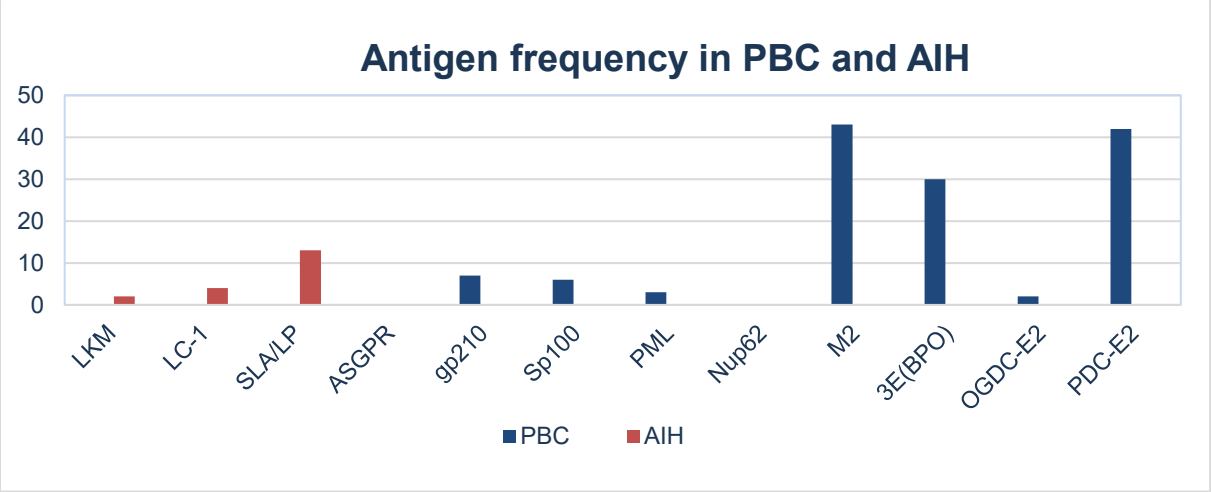
Name of Method	Catalog No.	Manufacturer	Antigens
EUROLINE - Autoimmune Liver Diseases IgG	DL 1300-1601-4 G	Euroimmun	AMA-M2, M2-3E, Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, and Ro52

Results

Table 2: Results on the Microblot-Array Liver profile reference samples

	Reference positive		
	Primary biliary cirrhosis (PBC)	**Autoimmune hepatitis (AIH)**	**Autoimmune liver diseases (AILD)**
Number of tested samples	44	19	63
Positive	44	13	63
Borderline (not evaluated)	0	0	0
Negative	0	0	0

	Reference negative		
	Healthy donors	**Infectious hepatitis**	**Autoimmune liver diseases (AILD)**
Number of tested samples	30	30	60
Positive	0	0	0
Borderline (not evaluated)	0	0	0
Negative	30	30	60



Picture 1: Antigen frequency in Primary biliary cirrhosis and Autoimmune hepatitis tested on Microblot-Array Liver profile kit

Table 3: Results of individual antigens in tested panels

	LKM	LC-1	SLA/LP	ASGPR	gp210	Sp100	PML	Nup62	M2	3E(BPO)	OGDC-E2	PDC-E2	Total
PBC (n=44)	0	0	0	0	**7**	**6**	**3**	0	**43**	**30**	**2**	**42**	**44**
	0%	0%	0%	0%	**16.3%**	**14%**	**7%**	0%	**100%**	**69.8%**	**4.7%**	**97.7%**	**100%**
AIH (n=19)	**2**	**4**	**13**	0	0	0	0	0	0	0	0	0	**19**
	10.5%	**21.1%**	**68.4%**	0%	0%	0%	0%	0%	0%	0%	0%	0%	**100%**
Viral hepatitis (n=30)	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	**0%**
RF-positive (n=30)	0	0	0	0	0	0	0	0	**2**	0	0	**3**	**4**
	0%	0%	0%	0%	0%	0%	0%	0%	**6.7%**	0%	0%	**10%**	**13.3%**
Donors (n=30)	0	0	0	0	0	0	0	0	0	0	0	0	**0**
	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	**0%**

Table 4: Results of clinical performance evaluation for the Microblot-Array Liver profile kit

	Parameter	Value	95% confidence interval (CI)
Diagnostic sensitivity	ALD (n = 63)	99.9%	94.3 – 100%
	PBC (n = 44)	99.9%	92.0 – 100%
	AIH (n = 19)	99.9%	82.4 – 100%
Diagnostic specificity (n = 60)		99.9%	94.0 – 100%
Positive predictive value	ALD (n = 63)	99.9%	94.3 – 100%
	PBC (n = 44)	99.9%	92.0 – 100%
	AIH (n = 19)	99.9%	82.4 – 100%
Negative predictive value	ALD (n = 60)	99.9%	94.0 – 100%
	PBC (n = 60)	99.9%	94.0 – 100%
	AIH (n = 60)	99.9%	94.0 – 100%
Likelihood ratios of the kit	Positive test (LR+)	>100	-
	Negative test (LR-)	<0.0001	-
Comparison with a reference method*		96.0%	91.5 - 98.5%

Clinical Benefit

- Diagnostic procedures based on immunoblot technologies detect antibodies associated with autoimmune liver diseases (ALD)
- Help identify the presence of ALD in patients with clinical suspicion
- The results support differentiation between different types of ALD
- The antibody profile is interpreted alongside the overall clinical picture

Conclusion

- Clinical performance was comparable to the reference method, with no significant differences
- Reliable performance was demonstrated under routine clinical conditions using clinical samples
- The kit achieves a diagnostic sensitivity and specificity of at least 60%.
- The assay fulfilled the manufacturer’s intended purpose intended for professional laboratory use in the diagnosis of autoimmune liver diseases using IgG antibodies in human serum or plasma