Clinical Performance Report: Microblot-Array Liver profile

(Abbreviated Version)[1]

The performance of the Microblot-Array Liver Profile IgG assay was evaluated through an external clinical performance study conducted at an independent specialized laboratory, the Institute of Rheumatology in Prague, Czech Republic. This evaluation was carried out in compliance with the strict requirements of the European In Vitro Diagnostic Medical Devices Regulation (IVDR).

The primary objective of the clinical study was to gather objective and reliable data on the performance of the newly developed assay under real clinical conditions.

Clinical Performance Parameters

The study assessed the following key characteristics of the assay's clinical performance:

- 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

The study used anonymized, archived residual samples from routine clinical testing, sourced from a general population indicated for IgG antibody testing for autoimmune disease diagnostics. Additionally, healthy blood donor samples and commercially available samples were included, ensuring the reliability and representativeness of the tested sample set.

Table 1**:** Tested samples

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

[1] The document is abbreviated and based on the original report on the clinical performance of Microblot-Array Liver profile CP559

[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

Results

Table 2: Results on the Microblot-Array Liver profile

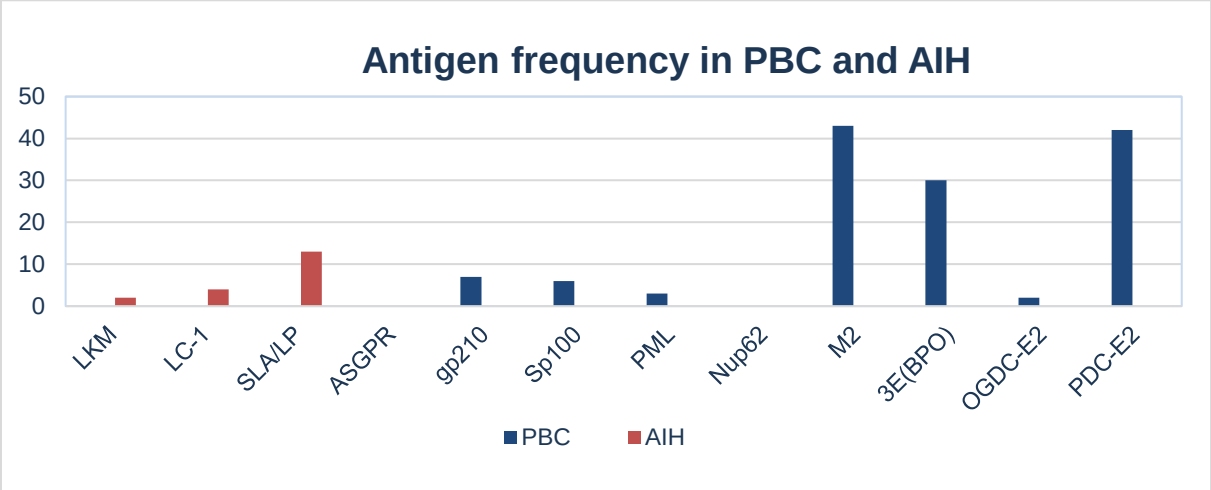
- Results of positive reference samples

	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*	0	0	0
Negative	0	0	0

- Results of negative reference samples

	Reference negative		
	Healthy donors	**Infectious hepatitis**	**Autoimmune liver diseases (AILD)**
Number of tested samples	30	30	60
Positive	0	0	0
Borderline*	0	0	0
Negative	30	30	60

*Not evaluated



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

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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%

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*Reference method for comparison of clinical performance

- EUROLINE - Autoimmune Liver Diseases - (IgG)
- Catalog Number: DL 1300-1601-4 G
- Manufacturer: Euroimmun Medizinische Labordiagnostika AG
- Antigens: AMA-M2, M2-3E, Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, and Ro52

Clinical Benefit

Diagnostic procedures based on the detection of antibodies against autoimmune liver diseases (ALD) using immunoblot technologies assist healthcare professionals not only in identifying the presence of ALD in suspected cases but also in differentiating the type of ALD. This information is then used in the context of the overall clinical picture to ensure appropriate medical care in accordance with applicable common standards in the EU.

Conclusion

The parameters obtained do not significantly differ from those obtained using the reference method. Borderline results were not evaluated.
The data meet the requirements for the clinical performance of the kit, which functions correctly with clinical samples in real clinical conditions, achieving a diagnostic sensitivity and specificity of at least 60%.
Based on the obtained values, the tested kit fulfils the intended purpose of use as defined by the manufacturer.
The diagnostic kit is used for diagnosing autoimmune diseases by detecting IgG antibodies against 13 different antigens (LKM-1, LC-1, SLA/LP, Sp100, gp210, ASGPR, PML, Nup62, M2, 3E(BPO), OGDC-E2, PDC-E2, and Ro52) in human serum or plasma from the general population.