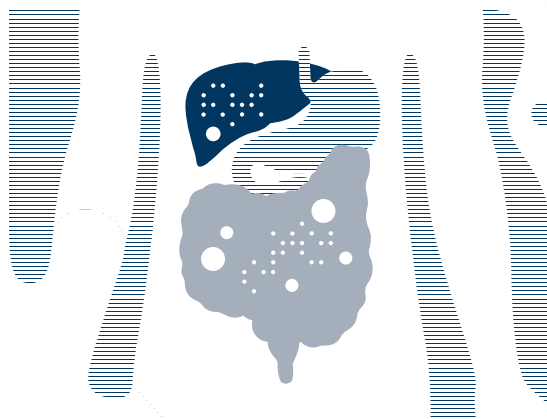


Microblot-Array

Liver profile



Focus:

Autoimmune hepatitis (AIH) and primary biliary cirrhosis (PBC)

Included in the kit 13 Antigens	
Liver profile	LKM-1, LC-1, SLA/LP, ASGPR, gp210, Sp100, PML, Nup62, M2, 3E (BPO), OGDC-E2, PDC-E2, Ro52
Autoimmune hepatitis	Liver Kidney microsomal type 1 LKM-1 <ul style="list-style-type: none"> – Associated with AIH2 and HCV – In AIH2, lower titers, especially important in pediatric patients
	Liver cytosol-1 LC-1 <ul style="list-style-type: none"> – Highly specific for AIH2 (30% of patients) – one of the diagnostic criteria for AIH2 – Associated with higher disease activity
	Soluble liver antigen/liver pancreas antigen SLA/LP <ul style="list-style-type: none"> – Associated with AIH3 or AIH1 (in about 25% of patients with chronic AIH) – Their presence depends on ethnicity
	Asialoglycoprotein receptor ASGPR <ul style="list-style-type: none"> – An important diagnostic marker of PBC – Also present in other liver diseases of viral origin – The level of antibodies correlates with the severity of the disease – Antibodies may disappear during immunosuppressive therapy
Primary biliary cirrhosis	Glycoprotein 210 gp210 <ul style="list-style-type: none"> – Associated with nuclear membrane – High specificity for PBC, especially in AMA negative patients (30–50%) – Association with a more severe PBC and a higher risk of developing cirrhosis – May also be associated with PSC
	Speckled protein 100 kDa sp100 <ul style="list-style-type: none"> – Associated with multiple nuclear dots – High specificity for PBC, probable association with progressive PBC and risk of fibrosis – Incidence in 30–50% of AMA negative patients
	Promyelocytic Leukemia Protein PML <ul style="list-style-type: none"> – Incidence in approximately 12–19% of PBC patients, association with PBC in AMA negative patients (predominantly in coexistence with anti-Sp100)
	Nucleoporin 62 Nup62 <ul style="list-style-type: none"> – High specificity for PBC, often simultaneously with anti-gp210 – Association with later stage disease and worse prognosis
	Intramitochondrial protein M2 <ul style="list-style-type: none"> – Binds anti-mitochondrial antibodies (AMA), highly sensitive – Typical for PBC, only in about 5-10% of PBC patients AMA is not formed – Overlapping syndromes with AIH – Rare occurrence in ANA patients (progressive SS, SjS or SLE)
	3E(BPO) Fusion protein (BCOADC E2 + PDC E2 + OGDC E2) <ul style="list-style-type: none"> – M2 subunits
	OGDC-E2 2-oxo-glutarate dehydrogenase complex <ul style="list-style-type: none"> – PDC-E2 is the dominant subunit (approx. 85–90% of cases)
	PDC-E2 Pyruvate dehydrogenase complex <ul style="list-style-type: none"> – PDC-E2 is the dominant subunit (approx. 85–90% of cases)
	TRIM21 Ro52 <ul style="list-style-type: none"> – Probable marker for PBC (occurs in approx. 28% of patients) – Associated with AIH1 (occurrence in approx. 38% of patients) – Diagnostic marker of SLE, SSc, specifically associated with myositis

PBS – Primary biliary cholangitis | **AIH1,2,3** – autoimmune hepatitis type 1, 2, 3 | **HCV** – hepatitis C virus |

PBC – primary biliary cirrhosis | **AMA** – antimitochondrial antibodies

Pre-launch testing

– Validation kit

Microblot-Array (MBA) Liver profile validation kit is a specialized, non-IVD kit, intended for the assessment of the performance and validation of the kit for future diagnostic applications.

Usage Limitations

Microblot-Array Liver profile validation kit is not certified under the In Vitro Diagnostic Regulation (IVDR) and is not intended for clinical diagnostic use. As such, it should not be used for providing results intended for patient management or clinical decision-making. Please note that future versions of the kit may or may not be developed and validated for in vitro diagnostic purposes under appropriate regulatory requirements.



Assay procedure

The assay procedure for MBA Liver Profile Validation Kit is the same as in the standard version. Serum and plasma can be used as a sample.

Step No.	Test steps
1.	Pipette Universal Solution – 150 µl
2.	Wells soaking at room temperature for 10 min.
3.	Aspirate off
4.	Dilute samples serum/plasma 1:51 (10 µl + 500 µl)
5.	Pipette control and diluted samples – 100 µl
6.	Incubate at room temperature for 30 min.
7.	Quick wash using the Universal Solution
8.	Aspirate and wash 3 x 5 min. with 150 µl of Universal Solution
9.	Pipette Conjugate – 100 µl
10.	Incubate at room temperature for 30 min.
11.	Quick wash using the Universal Solution
12.	Aspirate and wash 3 x 5 min. with 150 µl of Universal Solution
13.	Pipette Substrate Solution (BCIP/NBT) – 100 µl
14.	Incubate at room temperature for 15 min.
15.	Quick wash using the distilled water
16.	Aspirate and wash 2 x 5 min. with 200 µl of distilled water
17.	Dry and evaluate strips

**B
G** | **TestLine®**

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