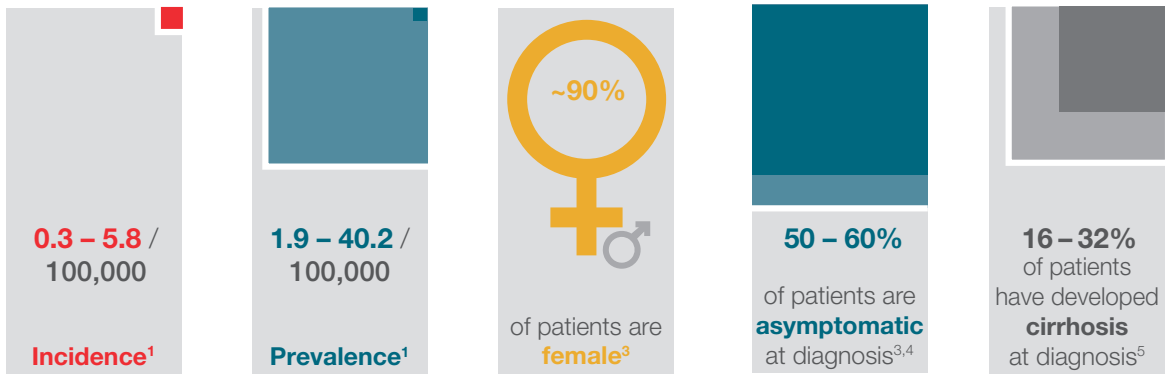# Flexible and automated testing for PBC

EliA M2 test

Primary biliary cholangitis (PBC)

Chronic inflammation of small intrahepatic bile ducts leading to impaired bile flow (cholestasis)[1,2]

**0.3 – 5.8 /
100,000**

Incidence[1]

**1.9 – 40.2 /
100,000**

Prevalence[1]

~90%

of patients are
female[3]

50 – 60%

of patients are
asymptomatic
at diagnosis[3,4]

16 – 32%

of patients
have developed
cirrhosis
at diagnosis[5]

Identifying patients with PBC enables the clinician to improve patients' quality of life

Anti-mitochondrial antibodies (AMA)

- Measurement of AMA is an important aid in the diagnosis of PBC[1]

- Often measured by immunofluorescence assay (IFA) that can be time-consuming and demanding in interpretation[1,2]

- Positive AMA IFA should be confirmed with a more specific anti-M2 enzyme immunoassay (EIA)[2]

- It has been reported that in 24–100% of AMA IFA negative samples AMA can be measured with EIA[6]

- AMA against different mitochondrial proteins (M1 through M9) have been identified[2,7]

- AMA against M2 (anti-M2) can be detected in ≥90% of PBC patients[1]

- M2 comprises several subunits with the pyruvate dehydrogenase complex representing the major antigen[8,9]

- In a comparative study, anti-M2 EIA using a mixture of native and recombinant M2 antigen has been reported to have a higher sensitivity than anti-EIA using either native or recombinant M2 antigen alone[10]

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Testing for anti-M2 antibodies

EliA™ M2 test – key features[11]

Antigen: native pyruvate dehydrogenase complex from mitochondria plus recombinant human M2-antigen

Controls: EliA™ M2 Positive Control and EliA™ IgG/IgM/IgA Negative Control

Automation: available for Phadia™ 100, 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™ LKM-1 test and EliA™ CTD Screen[12,13]

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

Clinical performance of EliA M2 test[14]

	Sensitivity [%]	Specificity [%]	PPV [%]	LR (+)
EliA M2 test (native M2 + recombinant M2)	81	98.1	95.3	42.5
Manufacturer 1 (native M2)	69	98.5	95.8	48.3
Manufacturer 2 (recombinant M2)	78	96.7	91.7	23.4

Study cohort: 100 PBC patients and 210 disease controls. PPV: Positive predictive value; LR(+): Positive likelihood ratio

- At a similar specificity, EliA M2 test had a higher sensitivity than the tests using only native or recombinant M2 antigen
- In a second study including 98 samples from PBC patients, EliA M2 test reported more positive samples than IFA (80 vs. 77)[15]

Technical data[11]

Ordering information	Article No.	Package size	Cut-off negative	Cut-off equivocal	Cut-off positive	Short name
EliA M2 Well	14-5649-01	4 x 12 wells	< 4 IU/ml	4–6 IU/ml	> 6 IU/ml	m2G

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8. Reshetnyak VI. Primary biliary cirrhosis: Clinical and laboratory criteria for its diagnosis. *World J Gastroenterol.* 2015;21(25):7683-708.
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11. Directions for Use, EliA M2 250-5649-021 / UK
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15. Thermo Fisher Scientific. Internal study.

Find out more at **thermofisher.com/elia**

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