Autoimmune Liver Disease

Primary Biliary Cirrhosis **PBC** - Autoimmune Hepatitis **AIH**

BlueDot Liver[7]

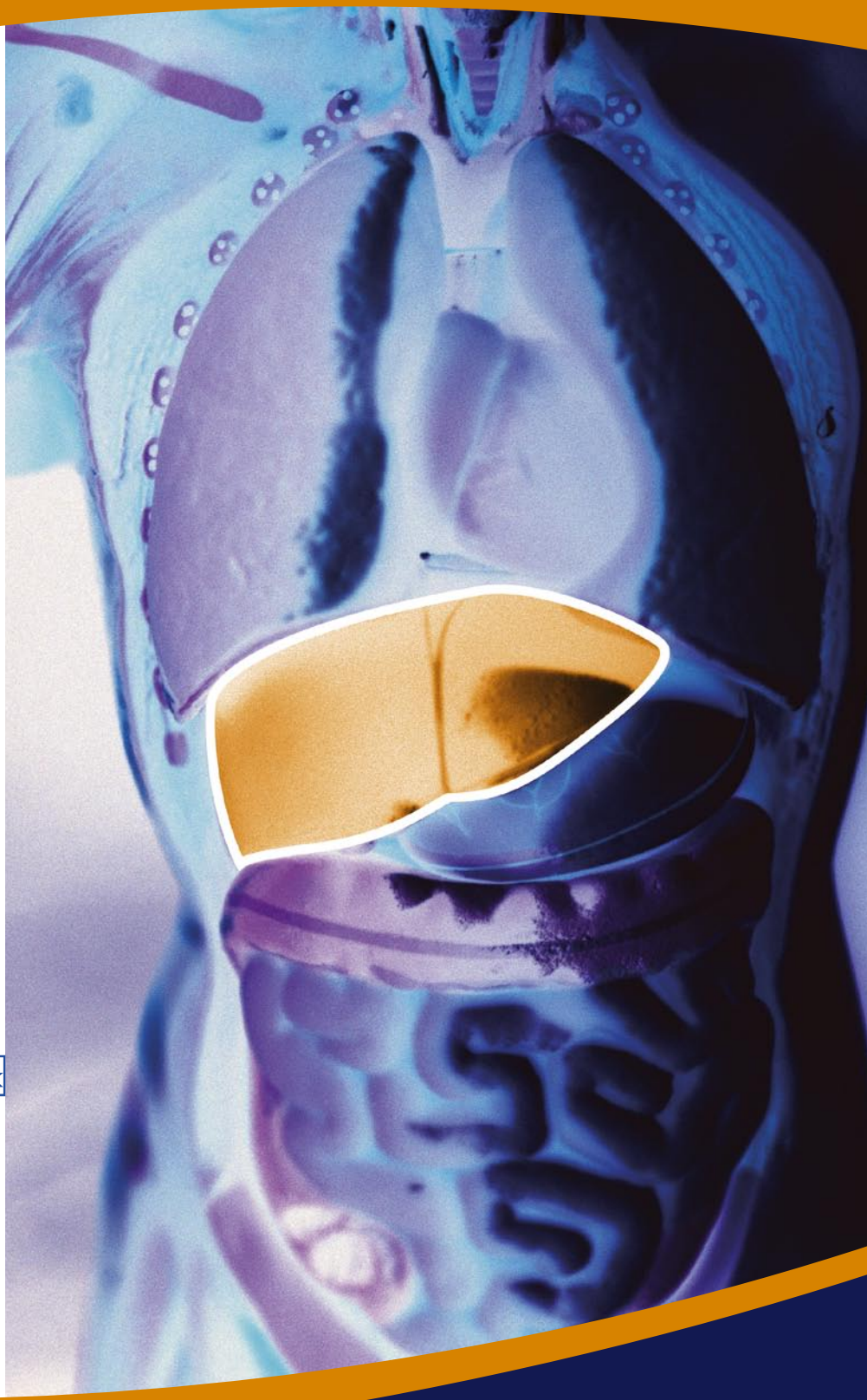
NEW

New BlueDot kit for the detection of liver-related IgG autoantibodies in human serum.

BlueDot

→**7** different PBC / AIH target antigens covered in one single test

- M2
- gp210
- sp100
- LKM1
- LC1
- SLA
- F-actin



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Autoimmune Liver Diseases are defined as immune mediated chronic liver diseases of unknown aetiology, including namely Primary Biliary Cirrhosis (**PBC**) and Autoimmune Hepatitis types 1 and 2 (**AIH-1 and 2**). PBC and AIH have long been considered rare diseases. Their incidence however has recently increased, probably because of a greater awareness of the diseases and the development of new diagnostic techniques.

Diagnosis

Diagnosis of AIH and PBC is based on a combination of clinical, biochemical, histological and serological findings. Apart from testing for markers of viral hepatitis (to rule out this cause), serology is mainly based upon screening for marker autoantibodies that are crucial for the correct diagnosis and classification of the diseases.

PBC-related antibodies

M2 - M2 antibodies belong to the group of antimitochondrial antibodies (AMA) and are strongly associated with PBC. At least nine distinct AMA have been identified, which have been classified M1-M9 according to their antigen specificity and disease association. Of these, only the M2 subtype seems to approach absolute specificity for PBC. Indeed, about 95 % of PBC patients have M2 autoantibodies and, conversely, about 90 % of asymptomatic individuals who are found to be M2-positive on routine screening can be shown to have underlying PBC on further investigations. The target antigens of M2 antibodies have been identified as components of the 2-oxo-acid dehydrogenase complex, the immunodominant epitopes being located on the E2 subunits of Pyruvate dehydrogenase complex (PDC-E2), Branched-chain oxoacid dehydrogenase complex (BCOADC-E2) and Oxoglutarate dehydrogenase complex (OGDC-E2).

gp210 and **sp100** - PBC patients usually display a variety of antinuclear antibodies (ANA), some of which overlapping with other systemic autoimmune diseases. In immunofluorescence assays, two labelling patterns however are typical for PBC : nuclear rim and multiple nuclear dots. Antibodies that are responsible for these patterns most often recognize the nuclear envelope glycoprotein gp210 and the nuclear body protein sp100, respectively. Although the clinical significance of these antibodies remains to be determined precisely, they are of particular utility in assessing PBC patients without antimitochondrial antibodies or with other atypical presentations. Moreover recent data indicate that, unlike M2 antibodies, PBC-specific ANAs correlate with disease severity and therefore may represent important markers of poor prognosis.

AIH-related antibodies

LKM1 (Liver Kidney Microsome) antibodies react with the microsomal cytochrome isoform P450 IID6 and are the most prevalent markers for type 2 AIH. They are considered specific for this type, although low titres of antibodies have been reported in about 5% of patients with chronic hepatitis C.

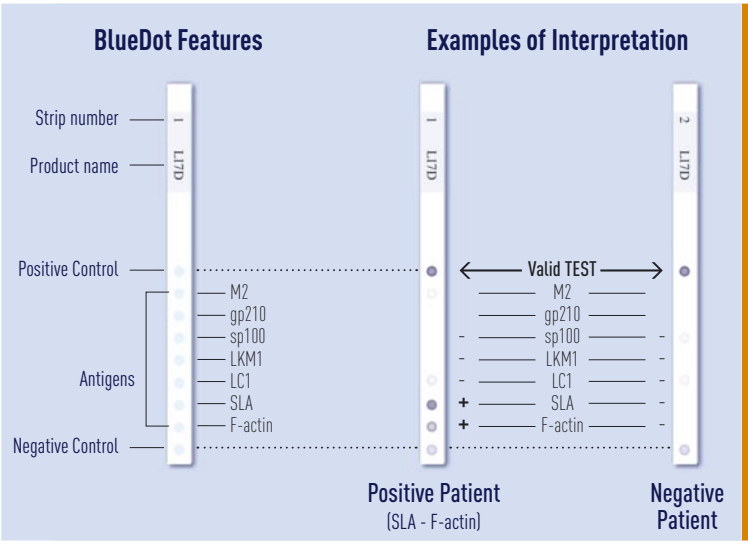
LC1 (Liver Cytosol) antibodies react with a soluble cytosol enzyme (Formiminotransferase Cyclodeaminase) and occur in about 30% of patients with type 2 AIH, though frequently associated with LKM1 antibodies, they are the sole liver-related circulating autoantibodies in about 10% of cases. Moreover anti-LC1 antibodies are clinically associated in most cases with greater disease activity and younger age.

SLA (Soluble Liver Antigen) antibodies seem to have a high positive predictive value for type 1 AIH, though relatively rare. However, they occur in a significant number of patients who are seronegative at presentation for other autoantibodies and therefore maybe useful diagnostically.

F-actin antibodies are the main component of the broad family of **S**mooth **M**uscle **A**ntibodies **(SMA)**. They bind to the F-actin component, a globular protein of 34kD (polymerized into filaments), in the cytoskeleton of the cells. F-actin in its biologically active polymerized form is the most specific and sensitive autoantigen of AIH Type 1. A correct interpreted F-actin pattern on ASMA is reported to have a sensitivity of ~90% and a specificity of ~100% for patients with acute phase AIH Type 1.

BlueDOT Liver[7]

BlueDot Liver[7] is a membrane immunoassay that allows to screen serologically for PBC and AIH. It offers easy handling and effective cost savings for the simultaneous detection of 7 different autoantibodies in one single test.



Available products and codes

Code	Product	Antigens
LI7D-24 24 tests	**BlueDot** Liver[7]	M2 • gp210 • sp100 • LKM1 LC1 • SLA • F-actin
LISD-24 24 tests	**BlueDot** Liver[5]	M2 • LKM1 • LC1 • SLA • F-actin
LID-24 24 tests	**BlueDot** Liver[3]	M2 • LKM1 • LC1
MI3D-24 24 tests	**BlueDot** Mitochondria[3]	PDH-E2 • OGDC-E2 • BCOADC-E2
MID-24 24 tests	**BlueDot** M2	M2 (PDH / OGDC / BCOADC mixture)