HEPATOLOGY *PRODUCT HIGHLIGHTS*

Liver diseases comprise several diseases and disorders causing liver malfunction and failure. In particular, an accurate differential diagnosis between viral and autoimmune hepatitis is crucial for the choice of an appropriate therapy.
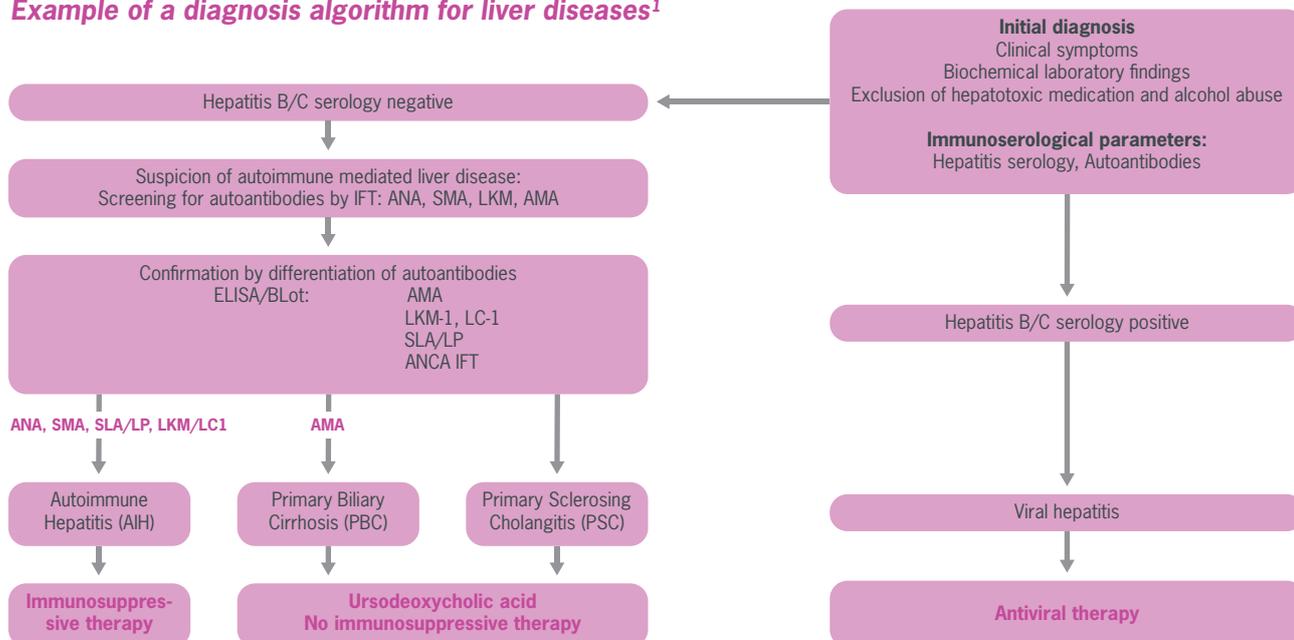
Autoimmune liver (hepatic) diseases include primary biliary cirrhosis (PBC), autoimmune hepatitis (AIH) and primary sclerosing cholangitis (PSC).
In autoimmune hepatitis (AIH) a chronic inflammation damages liver cells, while in PBC and PSC intrahepatic small bile ducts and large bile ducts, respectively, are affected by the patient's own immune system.

The *AESKULISA*® autoimmune liver disease panel offers a series of ELISA tests including anti-nuclear antibodies (ANA), anti-mitochondrial antibodies (AMA), anti-liver/kidney microsomal antibodies (LKM) and anti-soluble liver antigen/liver pancreas antigen (SLA/LP) antibodies.

The *AESKUSLIDES*® rat and mouse liver/kidney/stomach slides allow the detection of antibodies against smooth muscles (ASMA) – Autoimmune hepatitis Type I, antibodies against liver-kidney microsomes (LKM) – Autoimmune hepatitis Type II and antibodies against mitochondria (AMA) – Primary Biliary Cirrhosis (PBC).

Example of a diagnosis algorithm for liver diseases[1]

[1] Adapted and modified from an original algorithm from Czaja AJ and Norman GL. J Clin Gastroentero, 2003, 37: 315-329 by AESKU.DIAGNOSTICS.

A definite clinical diagnosis should not be based on the results of the performed tests alone, but should be made by the physician after all clinical and laboratory findings have been evaluated. The diagnosis is to be verified using different diagnostic methods..

AESKULISA® *Anti-mitochondrial autoantibodies (AMA):*

AMA are the most distinguishing serological feature to differentiate between AIH and PBC: AMA are present in up to 95% of PBC patients and specific for this disease. Moreover, AMA is a reliable predictive marker because they are often detectable years before clinical symptoms appear. Since the IgM subclass is the first to arise in an immune response, it is important to test not only for IgG but for IgM also, to reveal PBC at a very early stage. AESKU.DIAGNOSTICS also offers an AMA test as a combined IgG and IgM conjugate (*AESKULISA*® *AMA-M2-Check*).

AESKULISA® *soluble liver antigen/liver pancreas antigen (SLA/LP):*

AESKU.DIAGNOSTICS is the patent co-owner of the SLA/LP recombinant antigen identified by Wies et al. (Lancet, 2000). SLA/LP is the only autoantibody which is 100% specific for AIH but is not detectable in indirect immuno-fluorescence. Therefore, the use of an ELISA is mandatory.

It's specificity of 100% makes SLA/LP a unique and outstanding marker for AIH.

REF 3707 — AESKULISA® AMA-M2-Check

Conjugate:
anti-human IgG/M-HRP

Equivocal Zone:
16 - 24 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-Check

Antigens coated:
Native mitochondrial M2-antigen

Enzyme-linked immunoassay (ELISA) for the combined quantitative and qualitative determination of anti-mitochondrial IgG and IgM autoantibodies to M2 in human serum

REF 3705 — AESKULISA® AMA-M2-G

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Native mitochondrial M2-antigen

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of anti-mitochondrial IgG autoantibodies to M2 in human serum

REF 3706 — AESKULISA® AMA-M2-M

Conjugate:
anti-human IgM-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-M

Antigens coated:
Native mitochondrial M2-antigen

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of anti-mitochondrial IgM autoantibodies to M2 in human serum

REF 3702 — AESKULISA® LC-1

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Recombinant human Formiminotransferase cyclodeaminase

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to LC-1 in human serum

REF 3703 — AESKULISA® LKM-1

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Recombinant human cytochrome p450 2D6

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to liver-kidney microsomes (LKM-1) in human serum

REF 3704 — AESKULISA® SLA/LP

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Recombinant human soluble liver antigen/liver pancreas antigen (SLA/LP)

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to SLA/LP (soluble liver antigen/liver pancreas antigen) in human serum

AESKUBLOTS®

The **AESKUBLOTS®** test line represents a variety of different immunoblots for efficient profile testing of autoimmune and infectious diseases.
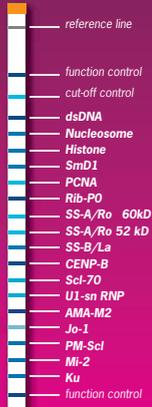
Coated with a selected panel of specific antigens on one test strip, **AESKUBLOTS®** provide a complete diagnostic overview in a single test and are suitable for screening of autoimmune diseases as well as cost-effective differential diagnosis.

For an easy automated processing the **HEL**MED® BLOT *processor can be used. For an easy semi-quantitative and automatic interpretation of AESKUBLOTS®, AESKU.SYSTEMS provides a dedicated evaluation software: AESKU.SCAN®.*

REF 4001

ANA-17 Pro

reference line
function control
cut-off control
dsDNA
Nucleosome
Histone
SmD1
PCNA
Rib-P0
SS-A/Ro 60kD
SS-A/Ro 52 kD
SS-B/La
CENP-B
Scl-70
U1-sn RNP
AMA-M2
Jo-1
PM-Scl
Mi-2
Ku
function control

AESKUBLOTS® ANA-17 Pro
24 tests/kit
Conjugate: anti-human IgG-HRP
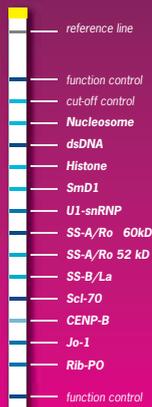Color-coded (orange) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:
dsDNA, nucleosomes, histones, SmD1, PCNA, Rib-P0, SS-A/Ro60kD, SS-A/Ro52kD, SS-B/La, CENP-B, Scl-70, U1-sn RNP, AMA-M2, Jo-1, Pm-Scl, Ku and Mi-2 in human serum.

AESKUBLOTS® ANA-17 Pro is used for the differential diagnosis of systemic rheumatic diseases. Detection of autoantibodies in **AESKUBLOTS®** with the corresponding specific antigens allows an easier and more reliable differentiation of specific ANAs (anti-nuclear antibodies). The ANAs included occur in active and inactive systemic lupus erythematosus (SLE), mixed connective tissue diseases (MCTD), scleroderma, Sjogren's syndrome, primary biliary cirrhosis (PBC) and polymyositis. **ANA-17 Pro** antigens are fitted on the test strip according to their relevance for the individual autoimmune disease (SLE, Sjogren's syndrome, CREST syndrome, scleroderma, MCTD, myositis, and PBC) allowing easier interpretation.

REF 4000

ANA-12 Pro

reference line
function control
cut-off control
Nucleosome
dsDNA
Histone
SmD1
U1-snRNP
SS-A/Ro 60kD
SS-A/Ro 52 kD
SS-B/La
Scl-70
CENP-B
Jo-1
Rib-P0
function control

AESKUBLOTS® ANA-12 Pro
24 tests/kit
Conjugate: anti-human IgG-HRP
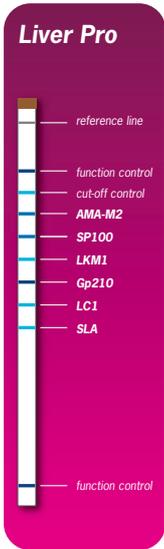Color-coded (yellow) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:
nucleosomes, dsDNA, histones, SmD1, U1-snRNP, SS-A/Ro60kD, SS-A/Ro52kD, SS-B/La, Scl-70, CENP-B, Jo-1 and ribosomal P protein (Rib-P0) in human serum.

AESKUBLOTS® ANA-12 Pro is used for the differential diagnosis of systemic rheumatic diseases. Detection of autoantibodies in **AESKUBLOTS®** with the corresponding specific antigens allows an easier and more reliable differentiation of specific ANAs (anti-nuclear antibodies). The ANAs included occur in active and inactive systemic lupus erythematosus (SLE), mixed connective tissue diseases (MCTD), scleroderma, Sjogren's syndrome and polymyositis.

AESKUBLOTS®

Liver Pro

REF 4004

- reference line
- function control
- cut-off control
- AMA-M2
- SP100
- LKM1
- Gp210
- LC1
- SLA
- function control

AESKUBLOTS® Liver Pro
24 tests/kit
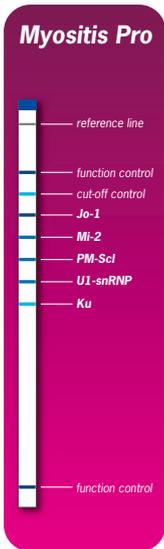*Conjugate:* anti-human IgG HRP
Color-coded (brown) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:
AMA-M2, Sp100, LKM1, gp210, LC1 and SLA in human serum.

AESKUBLOTS® Liver Pro is used as an aid in the diagnosis of autoimmune liver diseases. The most important autoimmune liver diseases are autoimmune hepatitis (AIH) types 1-3, primary biliary cirrhosis (PBC) and a combination of both diseases (immunocholangiopathy). AIH is a chronic, progressive liver disease of unknown cause, which responds well to immunosuppressive therapy, however, if untreated it has a poor prognosis. PBC is a chronic inflammatory disease of the small and medium-size bile ducts. Undetected it can lead to liver cirrhosis. An early and reliable diagnosis is therefore of great importance.

Myositis Pro

REF 4003

- reference line
- function control
- cut-off control
- Jo-1
- Mi-2
- PM-Scl
- U1-snRNP
- Ku
- function control

AESKUBLOTS® Myositis Pro
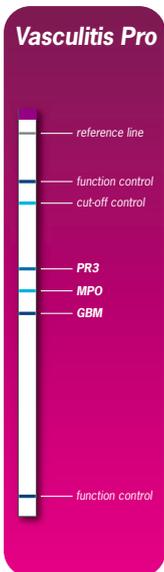24 tests/kit
Conjugate: anti-human IgG HRP
Color-coded (blue) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:
Jo-1, Mi-2, Pm-Scl, U1-snRNP and Ku in human serum.

AESKUBLOTS® Myositis Pro is designed to help in the diagnosis of poly- and dermatomyositis, as well as myositis-associated autoimmune diseases. Autoimmune myositis represents a heterogeneous group of acquired muscle diseases. Their main clinical and morphological characteristics are muscle weakness and inflammatory infiltration of skeletal muscles.

Vasculitis Pro

REF 4002

- reference line
- function control
- cut-off control
- PR3
- MPO
- GBM
- function control

AESKUBLOTS® Vasculitis Pro
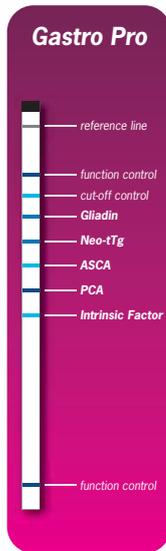24 tests/kit
Conjugate: anti-human IgG HRP
Color-coded (purple) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgG antibodies against:
PR3, MPO and GBM in human serum.

AESKUBLOTS® Vasculitis Pro is used for the differential diagnosis of autoimmune vasculitis. Antibodies against proteinase 3 (PR3) and myeloperoxidase (MPO) belong to the group of anti-neutrophil cytoplasmic antibodies (ANCA), which have been described as important markers in the differential diagnosis of autoimmune vasculitis. Anti-PR3 antibodies represent specific serological markers for granulomatosis with polyangiitis (Wegener's) and could play a role in pathogenesis. Anti-MPO antibodies occur in idiopathic and vasculitis-associated rapidly progressive glomerulonephritis, they are found in up to 70% of microscopic polyangiitis, and up to 5 - 50% in the Churg-Strauss syndrome. Serological detection of circulating antibodies against glomerular basement membrane in the glomeruli (GBM) is the method of choice in diagnosis of Goodpasture's syndrome.

Gastro Pro

reference line
function control
cut-off control
Gliadin
Neo-tTg
ASCA
PCA
Intrinsic Factor

function control

REF 4005

AESKUBLOTS® Gastro Pro
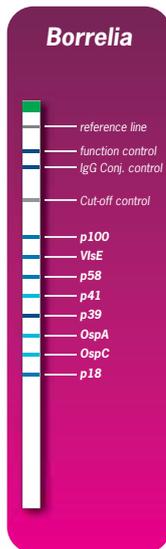24 tests/kit
Conjugate: anti-human IgA/IgG HRP
Color-coded (black) test strips with cut-off and positive control

Immunoblot for the qualitative detection of IgA and IgG antibodies against:
Gliadin, Neo-tTg, mannan (ASCA), parietal cells and Intrinsic factor-antigen.

AESKUBLOTS® Gastro Pro is designed to assist in the diagnosis of celiac disease, pernicious anemia and Crohn´s Disease. Each section of the gastro-intestinal tract can be affected by autoimmune gastrointestinal diseases. Disease is often diagnosed years after occurence of initial symptoms and outcome is severe in many cases.

Celiac patients often have an IgA deficiency. In order to avoid false-negative results, **AESKUBLOTS® Gastro Pro** detects IgA and IgG antibodies.

Borrelia

reference line
function control
IgG Conj. control

Cut-off control

p100
VlsE
p58
p41
p39
OspA
OspC
p18

REF 4006

AESKUBLOTS® Borrelia-G
24 tests/kit
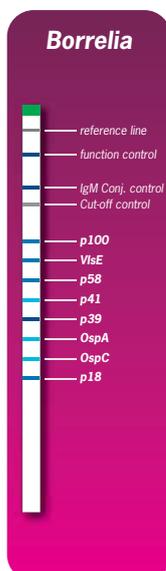**Conjugate:** anti-human IgG HRP
Color-coded (green) test strips with cut-off, positive and conjugate control

Immunoblot for the qualitative detection of specific **IgG** against *Borrelia burgdorferi* in human serum.

The assays provide tools for confirmation of positive and borderline ELISA (**AESKULISA® Borrelia-G**) results, and are in accordance with the two stage testing procedure recommended by the German Society for Hygiene and Microbiology (DGHM).

Lyme disease is a multisystemic disease caused by infection with the spirochete Borrelia burgdorferi, transmitted in Europe mainly by Ixodes ricinus (sheep tick). The antigens coated on the test strips are:
p100, VlsE, p58, p41, p39, OspA, OspC and p18.

Borrelia

reference line
function control

IgM Conj. control
Cut-off control

p100
VlsE
p58
p41
p39
OspA
OspC
p18

REF 4007

AESKUBLOTS® Borrelia-M
24 tests/kit
Conjugate: anti-human IgM HRP
Color-coded (green) test strips with cut-off, positive and conjugate control

Immunoblot for the qualitative detection of specific **IgM** against *Borrelia burgdorferi* in human serum.

The assays provide tools for confirmation of positive and borderline ELISA (**AESKULISA® Borrelia-M**) results, and are in accordance with the two stage testing procedure recommended by the German Society for Hygiene and Microbiology (DGHM).

Lyme disease is a multisystemic disease caused by infection with the spirochete Borrelia burgdorferi, transmitted in Europe mainly by Ixodes ricinus (sheep tick). The antigens coated on the test strips are:
p100, VlsE, p58, p41, p39, OspA, OspC and p18.