VASCULITIS PRODUCT HIGHLIGHTS

AESKU.DIAGNOSTICS offers a comprehensive and complete diagnostic portfolio in the field of vasculitis diagnostics.
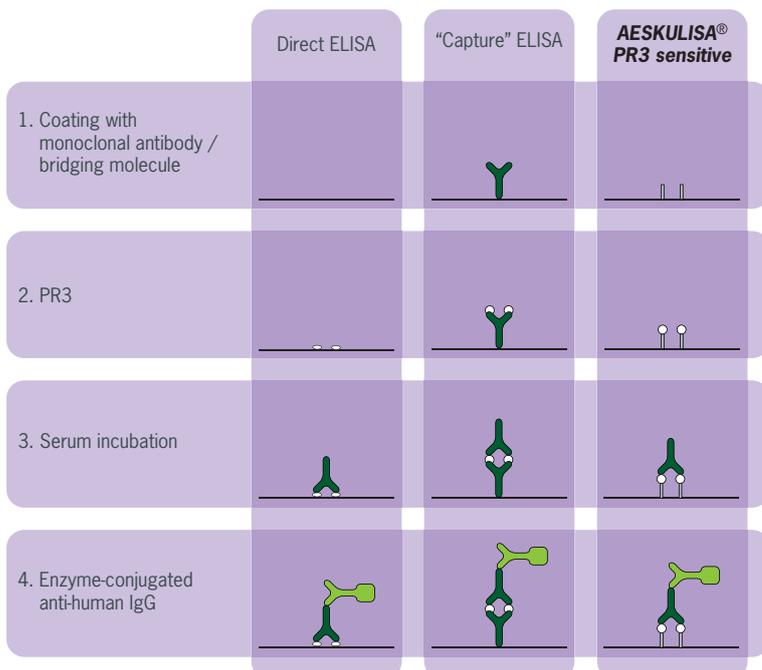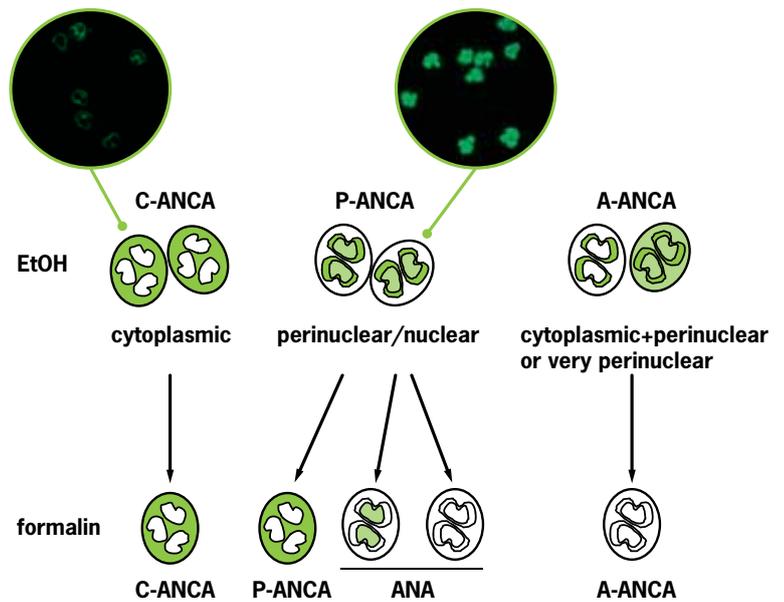
Not only are screening and profiling **AESKULISA**®s available but also does AESKU.DIAGNOSTICS supply the single parameters for the semi-quantitative analysis of patient sera. Complementing this, we also offer prime quality **AESKUSLIDES**® and **AESKUBLOTS**® which are an essential tool for the diagnosis of the respective vasculitis.

ANCA Testing

The anti-neutrophil cytoplasmic antibodies (ANCAs) consist of a range of antibodies which give rise to very specific immunofluorescence pattern termed C-ANCA (cytoplasmic) and P-ANCA (perinuclear) – the cytoplasmic C-ANCA pattern is a typical pattern usually indicating the presence of anti-proteinase 3 (PR3) antibodies.

The P-ANCA pattern, on the other hand, can be generated by antibodies against a plethora of antigens, the most important being antibodies against myeloperoxidase (MPO). In order to standardize the testing of ANCAs, a minimum requirement was defined in an international consensus statement (Savige et al. 1999). Here, ANCA testing demands an ELISA test following a positive IFT result.

Furthermore, the European Vasculitis Study Group (EUVAS) showed that the diagnostic specificity increases to 99% when the IFT is combined with an antigen-specific ELISA: e.g. C-ANCA and PR3-ELISA; P-ANCA and MPO-ELISA (Hagen et al. 1998).

AESKULISA® PR3 sensitive (REF 3302)

AESKU.DIAGNOSTICS scientists have developed an innovative method for the presentation of the antigen to the surface of the solid support, exposing a variety of relevant epitopes which would be hidden in the direct ELISAs, where the PR3 antigen is merely coated to the surface of the microtitre plate. This coating method, introduced in the **AESKULISA® PR3 sensitive** production since 2001, exposes all relevant epitopes for the binding of ANCAs and has been shown to be superior to direct ELISAs and compare very favorably with ELISAs based on the antibody capture techniques. (Trevisin et al. 2008; Radice et al. 2009; Csernok et al. 2010). Hence, **AESKULISA® PR3 sensitive** offers increased sensitivities and specificities compared to the commonly used direct ELISA setup.
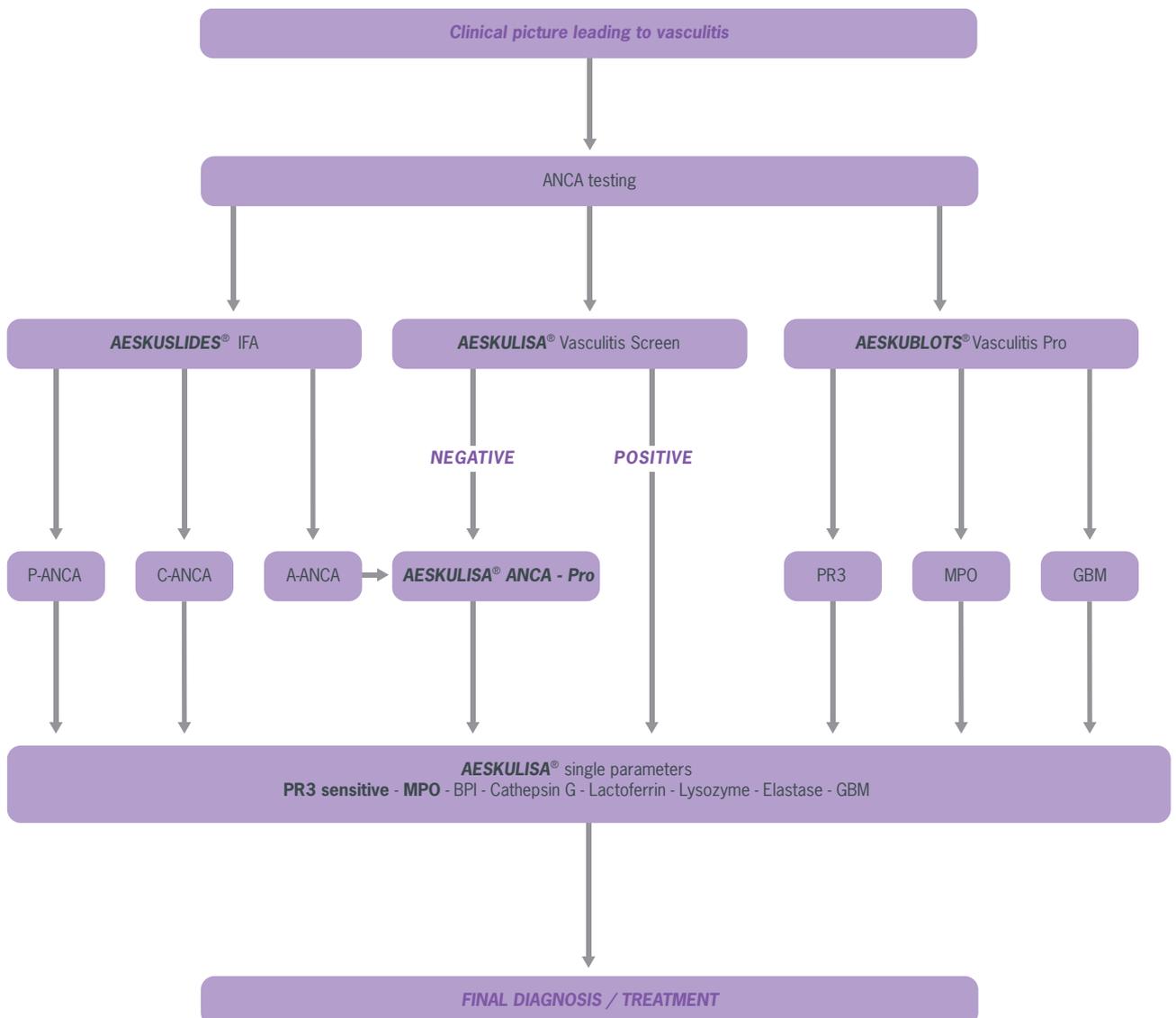
AESKULISA® *Vasculitis Screening (MPO+PR3)*

As an alternative to the IFT screening, AESKU.DIAGNOSTICS offers a screening test (*AESKULISA*® *Vasculitis-Screen*; REF 3323) which combines MPO and PR3 as antigens in one microtiter well for the rapid, simple and cost effective testing of ANCAs.

AESKULISA® ANCA PROFILE

Since many ANCA patterns, especially the P-ANCAs, can be caused by a variety of additional antigens like lactoferrin, cathepsin G, elastase, lysozym and bactericidal/permeability increasing protein (BPI), AESKU.DIAGNOSTICS offers a profiling ELISA test (*AESKULISA® ANCA-Pro*; REF 3301) for the rapid differentiation of these parameter.

To complete the portfolio, each of the profiling antigens can be quantified using the respective *AESKULISA®* against Lactoferrin (REF 3307), Cathepsin G (REF 3306), Elastase (REF 3305), Lysozyme (REF 3308) and BPI (REF 3304).

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.
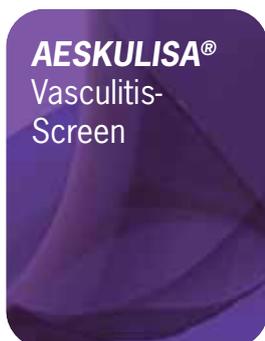
VASCULITIS

REF 3301 — AESKULISA® ANCA-Pro

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 100 U/ml

Kit Configuration:
Profile-G

Antigens coated:
Native human proteinase 3, myeloperoxidase, neutrophilic elastase, cathepsin G, lactoferrin, lysozyme, BPI

Enzyme-linked immunoassay (ELISA) for the separate semiquantitative or qualitative determination of IgG autoantibodies to 7 different cytoplasmic neutrophil antigens (PROFILE) in human serum

REF 3323 — AESKULISA® Vasculitis-Screen

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Screening-G

Antigens coated:
Each well with native human MPO and PR3

Enzyme-linked immunoassay (ELISA) for the combined quantitative and qualitative determination of IgG autoantibodies to myeloperoxidase (MPO) and proteinase 3 (PR3) in human serum (SCREENING)
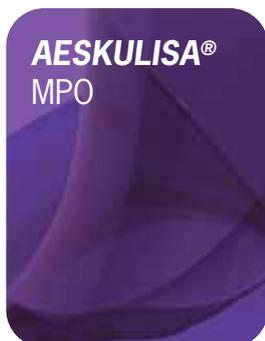
REF 3302 — AESKULISA® PR3 sensitive

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Native human proteinase 3

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to proteinase 3 (PR3) in human serum

REF 3303 — AESKULISA® MPO

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Native human myeloperoxidase

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

REF 3304 — AESKULISA® BPI

Conjugate:
anti-human IgG-HRP

Equivocal Zone:
12 - 18 U/ml

Standard Range:
0 - 300 U/ml

Kit Configuration:
Single-G

Antigens coated:
Native human BPI

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to BPI (bactericidal / permeability increasing protein) in human serum

REF 3305

AESKULISA®
Elastase

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Native human neutrophilic elastase

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

REF 3306

AESKULISA®
Cathepsin 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 human cathepsin G

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

REF 3307

AESKULISA®
Lactoferrin

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Native human lactoferrin

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

REF 3308

AESKULISA®
Lysozyme

Conjugate:
anti-human IgG-HRP
Equivocal Zone:
12 - 18 U/ml
Standard Range:
0 - 300 U/ml
Kit Configuration:
Single-G

Antigens coated:
Native human lysozyme

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

REF 3309

AESKULISA®
GBM

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 GBM

Enzyme-linked immunoassay (ELISA) for the quantitative and qualitative determination of IgG autoantibodies to recombinant human glomerular basement membrane protein (GBM) in human serum

AESKUBLOTS®

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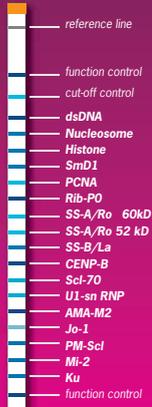
Coated with a selected panel of specific antigens on one test strip, **AESKUBLOTS®** provide a complete diagnostic overview in a single test and are suitable for screening of autoimmune diseases as well as cost-effective differential diagnosis.

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®*.*

ANA-17 Pro

REF 4001

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
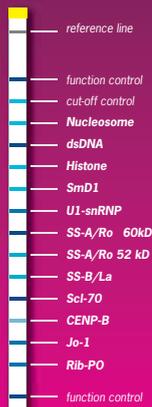Color-coded (orange) test strips with cut-off and positive control

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.

ANA-12 Pro

REF 4000

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
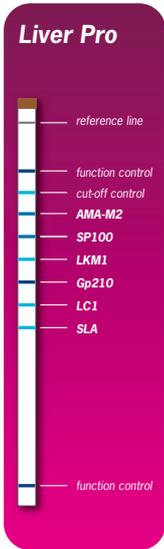Color-coded (yellow) test strips with cut-off and positive control

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
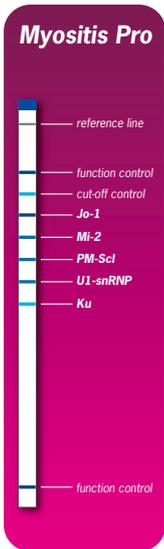**Conjugate:** anti-human IgG HRP
Color-coded (brown) test strips with cut-off and positive control

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
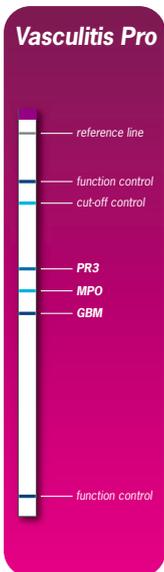**Conjugate:** anti-human IgG HRP
Color-coded (blue) test strips with cut-off and positive control

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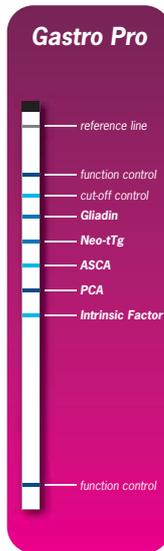24 tests/kit
Conjugate: anti-human IgG HRP
Color-coded (purple) test strips with cut-off and positive control

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.

AESKUBLOTS®

Gastro Pro

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

function control

REF 4005

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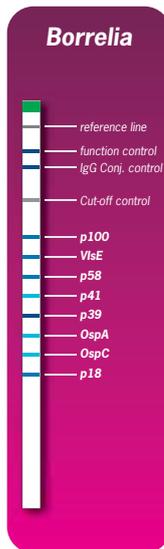24 tests/kit
Conjugate: anti-human IgA/IgG HRP
Color-coded (black) test strips with cut-off and positive control

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
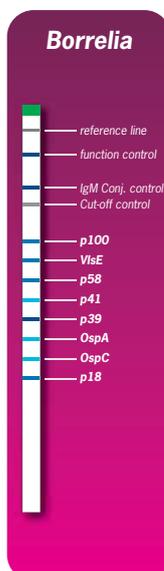**Conjugate:** anti-human IgG HRP
Color-coded (green) test strips with cut-off, positive and conjugate control

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.