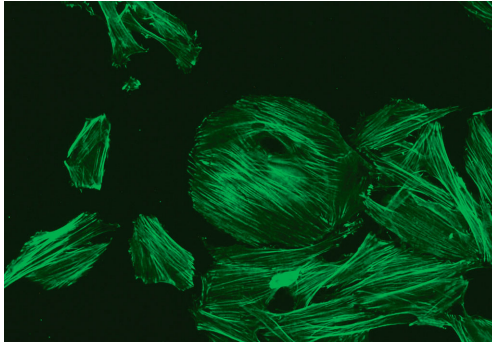
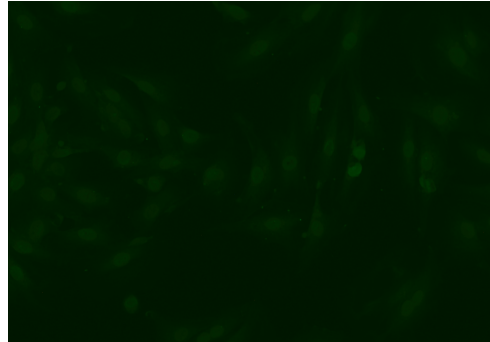




Anti-F-Actin IIFT



Positive reaction



Negative reaction

Antibodies against F-actin

Indication: Test system for the in vitro determination of antibodies against filamentous actin (F-actin) in human serum or plasma for the diagnosis of the following disease: Autoimmune hepatitis type I.

Clinical significance: The determination of antibodies against F-actin is of particular importance in the diagnosis of autoimmune hepatitis (AIH). AIH is an immune-mediated chronic inflammation of the liver. As most autoimmune diseases, AIH occurs more often in women (> 8%), particularly at the age of 10 to 30 and over 40 years. In a Norwegian study the incidence was determined as 0.1 to 1.9 cases per 100,000 inhabitants per year.

In around 40% of AIH patients the disease starts with acute symptoms. The main clinical symptoms are tiredness and weakness, followed by joint pain and arthritis, thyroiditis, diabetes mellitus and colitis. Conjunctivitis is additionally detected in around 25% of patients. The disease often progresses to liver cirrhosis. Hepatocellular carcinoma can also develop. The 10-year survival rate in severe cases is about 10%. Even with appropriate treatment there is a risk of early liver failure, usually within 6 months, for which a timely liver transplant must be considered. The 5-year survival rate after transplantation is around 90%.

In order to secure diagnosis and to exclude combined liver disease (overlap syndrome) it is essential to differentiate AIH from alcohol- or drug-induced cirrhosis and other chronic liver diseases. These include virus-induced hepatitis, primary biliary cirrhosis (PBC) and primary sclerosing cholangitis (PSC). Following anamnesis, clinical and machine-aided evaluation of the patient, liver function assays are performed, for example the determination of alkaline phosphatase, aspartate transaminase and alanine transaminase, as well as the determination of serum lipids. A liver biopsy is also usually indicated. A scoring system defined by the International Autoimmune Hepatitis Group (IAHG) is used to summarise and evaluate all diagnostic parameters with regard to the presence of AIH. In suspected cases of AIH, autoantibodies against smooth muscle (ASMA), in particular against F-actin, are analysed. These are detectable in around 50% of AIH patients. Supplementary tests are also required, above all tests for detection of autoantibodies against cell nuclei (ANA), against liver kidney microsome antigen 1 (LKM1; cytochrome P450IID6), against liver cytosolic antigen type 1 (LC1; enzyme: formiminotransferase cyclodeaminase) and against soluble liver antigen/liver pancreas antigen (SLA/LP).

Relevance of the Anti-F-Actin IIFT: High concentrations of antibodies against smooth muscle indicate AIH. One part of the antibodies is directed against conformational epitopes of F-actin, which are only present in frozen tissue sections or tissue cells and can therefore be detected neither by ELISA nor Western blot. In contrast to other ASMA, antibodies against F-actin represent a highly specific marker for AIH type I. The new cell line VSM47 (vascular smooth muscle) allows to quickly and reliably differentiate micro-filamentous (MF) fluorescence patterns from non-MF patterns, thus facilitating the diagnosis of AIH type I.

EUROIMMUN IIFT Autoimmune Diagnostics

tissue/cell substrates:
adrenal gland, monkey
bladder, rat
cartilage (trachea), monkey*
cerebellum, monkey
cerebrum, monkey
Crithidia luciliae
DNS-bound lactoferrin
erythrocytes, human*
eye, monkey*
granulocytes, human (ethanol-fixed)
granulocytes, human (formaldehyde-fixed)
granulocytes, human (methanol-fixed)
heart, monkey
HEp-2 cells
HEp-20-10 cells
HUVEC
hypothalamus, monkey*
intestine, monkey
kidney, monkey
kidney, mouse
kidney, rat
lacrimal gland, monkey
lip, monkey*
liver, monkey
liver, mouse
liver, rat
lobus temporalis, monkey*
lung, monkey
lymph nodes, monkey*
lymphocytes, human*
mammary gland, monkey*
mouth mucosa, monkey*
nerve, monkey
oesophagus, monkey
oesophagus, rat
ovary, monkey
pancreas, monkey
parathyroid gland, monkey
parotid gland, monkey
pituitary gland, monkey
placenta, monkey*
prostate, monkey
Saccharomyces cerevisiae
skeletal muscle, monkey
spermatozoa, human
spleen, monkey*
spinal cord, monkey
stomach, monkey
stomach, mouse
stomach, rat
synovium, monkey
testis, monkey
thrombocytes, human
thymus, monkey
thyroid gland, monkey
tongue, monkey
VSM47 cells
umbilical cord, human

EUROPLUS™ substrates:
AIH (LC-1 + SLA/LP)
BP180
GBM
gliadin
intrinsic factor
myeloperoxidase (MPO)
PBC (AMA M2 + Sp100)
proteinase 3 (PR3)
ribosomal P-proteins + Jo-1
SS-A + SS-B
SS-B + ribosomal P-proteins + Jo-1
SS-B + Scl-70 + Jo-1
thyroglobulin (TG)

transfected cells:
aquaporin-4
BP230
desmoglein 1 + 3
NMDA receptor
rPAG 1 + 2 (pancreas antigen 1 + 2)

BIOCHIP Mosaics™:
ANA global test: HEp-20-10/monkey liver
Autoantibody Profile: combination of 30 different tissues per slide
CIBD Profile: monkey pancreas/intest. goblet cells (culture)/granulocytes (EOH)/Saccharomyces cerevisiae
Basic Profile: HEp-20-10/monkey liver/rat kidney/rat stomach
EUROPLUS endomysium + gliadin: monkey intestine/monkey liver/gliadin
Granulocyte Mosaic: granulocytes (EOH)/granulocytes (HCHO)/HEp-2/monkey liver
Liver Mosaic: HEp-2/monkey liver/rat liver/rat kidney/rat stomach/monkey heart
Neuronal Antibody Screen: monkey cerebellum/monkey nerve/monkey intestine
Polyendocrinopathy Mosaic: monkey thyroid/monkey pancreas/monkey adrenal/monkey ovary/monkey testis/monkey stomach

Other mosaics also available
Special substrate combinations on request

* Currently not available as IVD in the EU.

Made in Germany



EUROIMMUN IIFT Infectious Serology

Viruses:

Adenoviruses
Chikungunya virus
Coxsackieviruses
Crimean Congo fever virus (CCHFV)*
Cytomegalovirus (CMV)
Dengue viruses types 1-4 (DENV)
ECHO virus
Epstein-Barr virus capsid antigen (EBV-CA)
Epstein-Barr virus early antigen (EBV-EA)
Epstein-Barr virus nuclear antigen (EBNA)
Hantaviruses (types Hantaan, Puumala, Seoul, Saaremaa, Dobrava, Sin Nombre, Andes*)
Herpes simplex virus types 1 and 2 (HSV-1/2)
Human herpes virus type 6 (HHV-6)
HIV-1 and -2*
Influenza virus A (Shangdong, Singapore, Beijing)
Influenza virus B (Panama)
Japanese encephalitis virus (JEV)*
Measles virus
Mumps virus
Parainfluenza viruses types 1-4
Respiratory syncytial virus (RSV)
Rubella virus*
Sandfly fever virus*
(types Sicilian, Naples, Toscana, Cyprus)
SARS Coronavirus (SARS-CoV)
Tick-borne encephalitis (TBE) virus
Varicella zoster virus (VZV)
West Nile virus (WNV)
Yellow fever virus (YFV)

Bacteria:

Afpipia felis*
Bartonella henselae
Bartonella quintana
Bordetella parapertussis
Bordetella pertussis
Borrelia afzelii
Borrelia burgdorferi
Borrelia garinii
Campylobacter coli*
Campylobacter jejuni*
Chlamydia pneumoniae
Chlamydia psittaci
Chlamydia trachomatis
Haemophilus influenzae*
Helicobacter pylori
Klebsiella pneumoniae*
Legionella bozemanii*
Legionella dumoffii*
Legionella gormanii*
Legionella jordanis*
Legionella longbeachae*
Legionella micdadei*
Legionella pneumophila serotypes 1-14
Listeria monocytogenes 1/2 a, 4b*
Mycoplasma hominis
Mycoplasma pneumoniae
Treponema pallidum
Treponema phagedenis
Ureaplasma urealyticum
Yersinia enterocolitica*

EUROPLUS™ substrates:

Borrelia VisE (recombinant)
Borrelia OspC
EBV p19 + gp125

Yeasts:

Candida albicans
Candida glabrata*
Candida krusei*
Candida parapsilosis*
Candida tropicalis*

Parasites:

Echinococcus granulosus
Leishmania donovani
Plasmodium falciparum HRP-2/MSR-2 (rec.)*
Plasmodium vivax MSP/CSP (recombinant)*
Toxoplasma gondii

Profiles:

Accompanying hepatitis profile
Central nervous system profile
Exanthema profile
Fever profile South East Asia
Flavivirus profile
Gastrointestinal tract profile
Infectarthritis profile
Infectarthritis profile (The Tropics)
Lymphadenitis profile
Myocarditis profile
Ophthalmology profile
Otitis profile
Pregnancy profile
Respiratory tract profile
Sexually transmitted diseases (STD) profile
TORCH profile

* Currently not available as IVD in the EU.

Special substrate combinations
on request

Made in Germany

Version: 02/10
FA_1651_D_UK_A03

Test characteristics Anti-F-Actin IIFT

Test principle: The present test system exclusively serves for the qualitative or quantitative in vitro determination of human antibodies in human serum or plasma. BIOCHIPS coated with VSM47 cells are incubated with diluted patient samples. In the case of positive reactions, specific antibodies of the class IgA, IgG and IgM will bind to the antigens. In a second step, the attached antibodies are stained with fluorescein-labelled anti-human antibodies and made visible with the fluorescence microscope.

Test procedure: EUROIMMUN BIOCHIP slides are incubated using the proprietary TITERPLANE™ Technique. This technique enables multiple samples to be incubated next to each other and simultaneously under identical conditions. Results are evaluated by fluorescence microscopy.

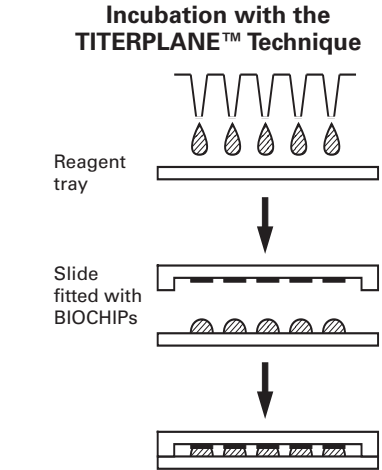
Intra-assay reproducibility: Ten determinations for each of two characterised samples were incubated in parallel. In quantitative evaluation of results, no deviation in the titer level was found.

Inter-assay reproducibility: Two characterised samples were incubated twice on at least 2 different days in 5 tests. In quantitative evaluation of results, no deviation in the titer level was found.

Inter-lot reproducibility: Positive and negative control sera were incubated on 3 different slide lots. The fluorescence intensities of the investigated IIFT resulted in deviations within the required specification of a maximum of +/- 1 intensity level.

Reference range: The antibody prevalence in 200 healthy blood donors (origin of sera: Germany) was 0.5% (titer 1:100 or higher).

Sensitivity and specificity: The clinical specificity of the test system is 95% and the clinical sensitivity 52%. Samples of patients with AIH type I (n = 33) and a control group (n = 104, origin of samples: Europe) were investigated. Reference: Villalta et al., Autoimmunity, 41:1, 105-110 (2008)



Panel	n	Anti-F-Actin IIFT positive
AIH type I	33	17 (52%)
AIH type II	8	0 (0%)
Hepatitis C	30	0 (0%)
Primary biliary liver cirrhosis	40	5 (13%)
Coeliac disease	16	0 (0%)
Liver steatosis	10	0 (0%)

Technical data:

Antigen substrate	VSM47 cells (vascular smooth muscle)
Sample dilution	Serum or plasma. Qualitative: 1:100, quantitative: 1:100/1000/10000 etc. There is no upper limit to the measurement range.
Conjugate	IgG
Test procedure	30 min (sample) / 30 min (conjugate). Room temperature.
Microscopy	Objektive 20x Excitation filter: 488nm, colour separator: 510nm, blocking filter: 520 nm, Light source: EUROIMMUN LED or mercury vapour lamp, 100 W
Reagents	Ready for use, with the exception of the PBS-Tween buffer.
Stability	18 months from the date of manufacture at +2°C to +8°C.
Kit formats	10 or 20 slides, each containing 3, 5 or 10 test fields. The kits include all necessary reagents.
Order no.	FA 1651-####
Related products	FA 1300-####-21 (HEp-2, liver/primate, kidney/rat, stomach/rat, F-actin, EUROPLUS (AMA-M2, Sp100, LC-1, SLA/LP))