

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Signatory to the Multilateral Agreements of
EA, ILAC and IAF for Mutual Recognition

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the medical laboratory

Klinisch-Immunologisches Labor Prof. Dr. Stöcker
Seekamp 31, 23560 Lübeck

is competent under the terms of DIN EN ISO 15189:2014 to carry out examinations in the following fields:

Medical Laboratory Diagnostics

Analytical Fields:

Immunology,
Microbiology,
Virology

The accreditation certificate shall only apply in connection with the notice of accreditation of 18.09.2017 with the accreditation number D-ML-13400-01 and is valid until 17.09.2022. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

Registration number of the certificate: **D-ML-13400-01-00**

Frankfurt am Main,
18.09.2017

Dipl.-Biol. Uwe Zimmermann
Head of Division

Translation issued:
18.09.2017


Head of Division

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The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkKS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkKS.

DAkKS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:

EA: www.european-accreditation.org

ILAC: www.ilac.org

IAF: www.iaf.nu

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-13400-01-00 according to DIN EN ISO 15189:2014

Period of validity: 18.09.2017 bis 17.09.2022

Date of issue: 18.09.2017

Holder of certificate:

Klinisch-Immunologisches Labor Prof. Dr. Stöcker
Seekamp 31, 23560 Lübeck

Examination in the field:

Medical Laboratory Diagnostics

Examination areas:

Immunology
Mikrobiologie
Virology

Within the given examination field marked with *, the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the free choice of standard or equivalent examination procedures.

The listed examination procedures are exemplary. The medical laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Examination area: Immunology

Examination field:

Ligand assays*

Analyte (measurand)	Examination material (matrix)	Examination technique
AMA M2-3E IgG	serum, plasma	ELISA
Anti-CCP (cyclic citrull. peptides) IgG	serum, plasma	ELISA
Anti-dsDNS-NCX IgG	serum, plasma	ELISA
Anti-GBM (glomerular basement membrane) IgG	serum, plasma	ELISA
Anti-Gliadin-GAF-3X IgA, IgG	serum, plasma	ELISA
Anti-MPO (Myeloperoxidase) IgG	serum, plasma	ELISA
Anti-PR3-hn-hr (Proteinase3) IgG	serum, plasma	ELISA
Anti-BP180 (NC16A-4x) IgG	serum, plasma	ELISA
Anti-Endomysium (Transglutaminase) IgG	serum, plasma	ELISA
Anti-Jo-1 IgG (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-Ribosomales P-Protein IgG (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-Scl-70 (DNS Topoisomerase I) (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-Sm IgG (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-SS-A (Ro) 60 kDa (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-SS-B (La) IgG (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-U1-(n) RNP/Sm IgG (ENA Profile Plus 2)	serum, plasma	ELISA
Anti-Zentromere IgG (ENA Profile Plus 2)	serum, plasma	ELISA
AMA-M9 IgGM	serum, plasma	EIA (EUROASSAY)
Anti-RP155 IgG (Systemsclerosis Profile)	serum, plasma	EIA (EUROLINE)
Anti-SLA/LP IgG (Autoimmune)	serum, plasma	EIA (EUROLINE)
Anti-GQ1b IgG, IgM (Gangliosid Profile 2)	serum, plasma	EIA (EUROLINE)
Anti-HEP-2-cell-antigens IgG	serum, plasma	EIA (EUROLINE/ Westernblot)
Anti-d2 Derm. farinae	serum, plasma	ELISA (Allercoat)
profile food (f1, f75, f2, f45, f4, f5, f9, f13, f14, f17, f20, f49, f84, f237, f25, f31, f35, f85, f3, f23, CCD)	serum, plasma	EIA (EUROLINE)
Anti-Acetylcholine receptores IgG	serum, plasma	RIA
Anti-Calcium-Channel PQ-type IgG	serum, plasma	RIA
Anti-Potassium channels	serum, plasma, liquor	RIA
Anti-Muscle-specific tyrosinekinase	serum, plasma	RIA
CXCL-13	serum, plasma	ELISA

Analyte (measurand)	Examination material (matrix)	Examination technique
TRAb (TSH receptor) IgG	serum, plasma	ELISA
Circ. immunocomplexes C1q	serum, plasma	ELISA

Examination field:

Microscopy*

Analyte (measurand)	Examination material (matrix)	Examination technique
AMA IgG (autoantibodies against mitochondria)	serum, plasma	IIFT
ANA IgG (autoantib. against cell nucleus) IF-global test	serum, plasma	IIFT
cANCA IgG	serum, plasma	IIFT
Anti-CASPR2 IgG	serum, plasma	IIFT
Anti-Endomysium IgA, IgG	serum, plasma	IIFT
Anti-Glutamate receptor (type NMDA) IgG	serum, plasma, CSF	IIFT
Anti-Hu IgG (ANNA-1)	serum, plasma	IIFT
Anti-ICA IgG	serum, plasma	IIFT
Anti-LKM-1 IgG	serum, plasma	IIFT
Anti-Adrenal cortex IgAGM	serum, plasma	IIFT
pANCA IgA, IgG	serum, plasma	IIFT
Anti-Pancreas-acini (CUZD1, GP2) IgA, IgG	serum, plasma	IIFT
Anti-PLA2R (Phospholipase A2-Receptor) IgG	serum, plasma	IIFT
Anti-Thrombocytes, free IgA,G,M	EDTA blood, plasma	IIFT

Examination field:

Molecular biological analysis (amplification techniques)

Analyte (measurand)	Examination material (matrix)	Examination technique
HLA-B27	EDTA blood	Microarray (EUROArray)
HLA-B57:01	EDTA blood	Microarray (EUROArray)
HLA-Cw6	EDTA blood	Microarray (EUROArray)
HLA-DQ2/DQ8	EDTA blood	Microarray (EUROArray)

Examination area: Mikrobiology

Examination field:

Ligand assays*

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-Borrelia IgM	serum, plasma	ELISA
Anti-Borrelia plus VlsE IgG	serum, plasma	ELISA
Anti-Toxoplasma gondii IgA, IgM	serum, plasma	ELISA
Anti-Borrelia CSF/serum-quotient IgG	serum, CSF	ELISA
Anti-Borrelia-RN-AT IgG, IgM	serum, plasma	EIA (EUROLINE)
Anti-Yersinia enterocolitica IgA, IgG	serum, plasma	EIA (Westernblot)
Anti-Helicobacter pylori IgA, IgG	serum, plasma	EIA (EUROLINE-Westernblot)

Examination field:

Mikroskopie*

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-Chlamydia MIF pneumoniae/trachomatis/psittaci IgA, IgG, IgM	serum, plasma	IIFT
Anti-Helicobacter pylori IgA, IgG	serum, plasma	IIFT
Anti-Toxoplasma gondii IgG, IgM	serum, plasma	IIFT

Examination area: Virology

Examination field:

Ligand assays*

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-Rubella virus IgG avidity	serum, plasma	ELISA
Anti-Rubella virus CSF/serum-quotient IgG	serum, CSF	ELISA
Anti-CMV IgG, IgM (TO.R.C.H. Profile)	serum, plasma	EIA (EUROLINE)
Anti-Rubella virus IgG	serum, plasma	EIA (Westernblot)
Anti-HSV C1, G1+G2 IgG, IgM	serum, plasma	EIA (EUROLINE-Westernblot)

Examination field:

Mikroskopie*

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-EBV sequence (CA/EA/EBNA-1) IgG, IgM	serum, plasma	IIFT
Anti-EBV-CA IgG avidity	serum, plasma	IIFT
Anti-Hanta Virus IgG, IgM	serum, plasma	IIFT