

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
Am Sonnenberg 9, 23627 Groß Grönau

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

Medical Laboratory Diagnostics

Medical laboratory fields:

Immunology
Microbiology
Virology

The accreditation certificate shall only apply in connection with the notice of accreditation of 23.11.2021 with the accreditation number D-ML-13400-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

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

Deutsche Akkreditierungsstelle GmbH

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

Valid from: 23.11.2021

Date of issue: 23.11.2021

Holder of certificate:

**Klinisch-Immunologisches Labor Prof. Dr. Stöcker
Am Sonnenberg 9, 23627 Groß Grönau**

Examinations in the field:

Medical laboratory diagnostics

Medical laboratory fields:

Immunology
Microbiology
Virology

Within the given type of examination marked with *, the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the free choice of standards 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.

The requirements for the management system in DIN EN ISO 15189 are written in a language that is relevant for medical laboratories and are generally in accordance with the principles of DIN EN ISO 9001.

*The certificate, including the annex, reflects the status at the time of the date of issue. The current status of the scope of the accreditation can be found in the database of accredited bodies of the German Accreditation Body (DAkkS).
<https://www.dakks.de/content/datenbank-akkreditierter-stellen>*

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-Transglutaminase (endomysium) 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-dsDNA IgG (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-Histones IgG (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-Scl-70 (DNA Topoisomerase I) (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-Sm IgG (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-SS-A (Ro) 60 kDa (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-SS-B (La) IgG (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-U1-(n) RNP/Sm IgG (ENA SLE Profile 2)	serum, plasma	ELISA
Anti-LKM-1 IgG (Liver Antigen Profile)	serum, plasma	EIA (EUROASSAY)
Anti-RP155 IgG (ANA Profile, Systemic sclerosis Profile)	serum, plasma	EIA (EUROLINE)
Anti-SLA/LP IgG (Autoimmune Liver diseases Profile)	serum, plasma	EIA (EUROLINE)
Anti-GQ1b IgG, IgM (Gangliosid Profile 2)	serum, plasma	EIA (EUROLINE)
Profile Inhalation (g1, g3, g6, g12, t2, t3, t4, t7, w1, w8, w6, w9, d1, d2, es4, e2, e3, e6, e1, e82, e84, m1, m2, m3, m6, CCD)	serum, plasma	EIA (EUROASSAY)
Profile Food 3 (f13, f17, f20, f158, f12, f14, f89, f96, f25, f47, f48, f85, f49, f84, f92, f95, f26, f27, f83, f3, f23, f24, f40, f4, f8, f9, f10, f45, f2, f78, f218, f1, f75, CCD)	serum, plasma	EIA (EUROLINE)

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-Acetylcholine receptors IgG	serum	RIA
Anti-Calcium channels PQ type IgG	serum, plasma	RIA
Anti-Potassium channels	serum	RIA
CXCL-13	CSF	ELISA
TRAk (TSH receptor) IgG	serum	ELISA
Circ. immune complexes C1q	serum, EDTA plasma	ELISA

Examination field:

Ligand assays

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-Potassium channels	CSF	RIA
Anti-MuSK (muscle specific tyrosine kinase) IgG	serum	RIA
Anti-Nucleosomes IgG (ENA SLE Profile 2)	serum, plasma	ELISA

Examination field:

Microscopy*

Analyte (measurand)	Examination material (matrix)	Examination technique
AMA IgG (autoantibodies against mitochondria)	serum, plasma	IIFT
ANA IgG (autoantibodies 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 IgG	serum, plasma	IIFT
pANCA IgA, IgG	serum, plasma	IIFT
Anti-Pankreas acini (CUZD1, GP2) IgA, IgG	serum, plasma	IIFT
Anti-PLA2R (phospholipase A2-receptor) IgG	serum, plasma	IIFT
Anti-Thrombocytes, free IgG	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: Microbiology

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
CXCL-13	CSF	ELISA
Anti-Toxoplasma gondii IgA	serum, EDTA plasma	ELISA
Anti-Toxoplasma gondii 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:

Microscopy*

Analyte (measurand)	Examination material (matrix)	Examination technique
Anti-Chlamydia MIF pneumoniae/trachomatis/psittaci IgA, IgG, IgM	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-SARS-CoV-2 spike protein IgA, IgG	serum, plasma	ELISA
Anti-SARS-CoV-2-NCP IgG	serum, plasma	ELISA
Anti-Rubella virus IgG avidity	serum, plasma	ELISA

Analyte (measurand)	Examination material (matrix)	Examination technique
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:

Microscopy*

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

Examination field:

Molecular biological analysis (amplification techniques)

Analyte (measurand)	Examination material (matrix)	Examination technique
SARS-CoV-2	throat swabs	RT-PCR (EURORealTime)