

Accreditation



The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the proficiency testing provider

EUROIMMUN Medizinische Labordiagnostika AG
Institut für Qualitätssicherung Lübeck
Seekamp 31, 23560 Lübeck

meets the requirements according to DIN EN ISO/IEC 17043:2010 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the proficiency testing provider, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO/IEC 17043 are written in the language relevant to the operations of proficiency testing providers and confirm generally with the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notices of 16.06.2023 with accreditation number D-EP-13423-01.

It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 3 pages.

Registration number of the accreditation certificate: **D-EP-13423-01-00**

Berlin, 16.06.2023

Dr.-medic Simona Curelea
Head of Technical Unit

Translation issued:
30.08.2023



Dr.-medic Simona Curelea
Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

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

See notes overleaf

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-EP-13423-01-00 according to DIN EN ISO/IEC 17043:2010

Valid from: 16.06.2023

Date of issue: 30.08.2023

Holder of accreditation certificate:

EUROIMMUN Medizinische Labordiagnostika AG
Institut für Qualitätssicherung Lübeck

at the locations

Seekamp 31, 23560 Lübeck
Werkstraße 1, 23942 Dassow

The proficiency testing provider meets the requirements of DIN EN ISO/IEC 17043:2010 to carry out the conformity assessment activities listed in this annex. The proficiency testing provider meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17043 are written in the language relevant to the operations of proficiency testing providers and confirm generally with the principles of DIN EN ISO 9001.

Proficiency testing in the following field:

Medical Laboratory Diagnostics

Investigation Fields:

Immunology, Microbiology, Virology

Using the proficiency testing materials:

Serum, Plasma, Plasmapherisate

The proficiency testing provider maintains a current list of all proficiency tests in the field of accreditation.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de>.

Abbreviations used: see last page

Page 1 of 3

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

Investigation Field: Immunology

Testing field	Matrix/ Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Autoimmunity	Serum, Plasma Plasmapherisate	Antibodies and/or antigens	Autoantibodies against acetylcholine receptors (AChR), Autoantibodies against cell nuclei (ANA), Autoantibodies against granulocytes (ANCA), Antibodies against CCP, Autoantibodies in diabetes, Autoantibodies against structural proteins of the skin, Antibodies in autoimmune liver diseases, Antibodies in autoimmune myopathies, Autoantibodies against neuronal antigens, Antibodies in autoimmune kidney diseases, Autoantibodies in pernicious anaemia, Autoantibodies against phospholipids, Autoantibodies against thyroid gland, Antibodies against tissue transglutaminase (tTG), endomysium and gliadin (celiac disease)
Allergology	Serum, Plasma, Plasmapherisate	Antibodies and/or antigens	Total IgE, Allergology: Specific IgE Molecular allergology: Specific IgE

* exemplary list

Investigation Field: Microbiology

Testing field	Matrix/ Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Infectious serology	Serum, Plasma, Plasmapherisate	Antibodies and/or antigens	Antibodies against <i>Borrelia burgdorferi</i> sensu lato

* exemplary list

Valid from: 16.06.2023

Date of issue: 30.08.2023

Investigation Field: Virology

Testing field	Matrix/Products	Test parameters/ Analytes*	Proficiency Testing Programs*
Infectious serology	Serum, Plasma, Plasmapherisate	Antibodies and / or antigens	Antibodies against Chikungunya virus, Antibodies against Dengue virus, Antibodies against Epstein-Barr virus, Antibodies against Hepatitis E virus, Antibodies against Herpes simplex virus, Antibodies against Measles virus, Antibodies against Parvovirus B19, Antibodies against SARS-CoV-2, Antibodies against Zika virus

* exemplary list

Abbreviations used:

- DIN Deutsches Institut für Normung e.V. – German institute for standardization
- EN Europäische Norm – European Standard
- IEC International Electrotechnical Commission
- ISO International Organization for Standardisation