

Accreditation



The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that

Medicum Bad Aibling MVZ GmbH
Rosenheimer Str. 6-8, 83043 Bad Aibling

operates a medical laboratory that fulfills the requirements according to DIN EN ISO 15189:2024 for those conformity assessment activities specified in detail in the annex listed below. This includes additional existing legal and normative requirements for the medical laboratory including those in relevant sectoral schemes, provided that these are explicitly confirmed in the annex listed below.

D-ML-22296-01-01 Valid from: 11.12.2025

The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories and they conform to 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 notice of 11.12.2025. It consists of this cover sheet, the reverse side of the cover sheet and the corresponding annex .

Registration number of the accreditation certificate: **D-ML-22296-01-00**

Berlin, 11.12.2025 Dipl.-Ing Anna Lewandowski | Head of Department

Translation issued: 01.09.2026

This accreditation certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS). It is digitally sealed and valid without signature. It reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

The Deutsche Akkreditierungsstelle GmbH (DAkKS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkKS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

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 Co-operation (ILAC).

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

Annex to the accreditation certificate D-ML-22296-01-01 according to DIN EN ISO 15189:2024

Valid from: 11.12.2025

Date of issue: 01.09.2026

This certificate annex is part of accreditation certificate D-ML-22296-01-00.

Holder of accreditation certificate:

**Medicum Bad Aibling MVZ GmbH
Rosenheimer Str. 6-8, 83043 Bad Aibling**

with the location

**Medicum Bad Aibling MVZ GmbH
Zirbelstr. 58, 86154 Augsburg**

The medical laboratory meets the requirements pursuant to DIN EN ISO 15189:2024 necessary to carry out the conformity assessment activities set out in this annex. The medical laboratory meets, where applicable, additional legal and normative requirements, including those set out in relevant sectoral schemes, provided that these are expressly confirmed below.

The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories. Laboratories that conform to the requirements of this standard operate generally according to the principles of DIN EN ISO 9001.

*This certificate annex was issued by Deutsche Akkreditierungsstelle GmbH and is digitally sealed.
It is valid only together with the certificate issued in writing and reflects the status as indicated by the date of issue.
The current status of the valid and monitored accreditation can be found in the database of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de)*

Annex to the accreditation certificate D-ML-22296-01-01

Examinations in the field:

Medical laboratory diagnostics

Medical laboratory fields:

Clinical chemistry

Immunology

Microbiology

Virology

Flexible Scope of Accreditation:

Within the indicated examination fields the medical laboratory is permitted without being required to prior inform and obtain approval from DAkkS

[Flex B] to have the free choice from standardised or equivalent examination methods.

[Flex C] to modify, develop or further develop examination methods.

The examination methods listed are examples. The medical laboratory has an up-to-date list of all examination methods within the flexible scope of accreditation. The list is publicly available on the website of the medical laboratory.

Medical laboratory field: Clinical chemistry

Type of examination:

Ligand assays ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
25-OH-vitamin D	Serum	ELISA

Medical laboratory field: Immunology

Type of examination:

Flow cytometry ^[Flex C]

Analyte (measurand)	Test material (matrix)	Test technique
CD3, CD19, CD45, CD56, CD57	EDTA blood, heparin blood	Flow cytometry

Type of examination:

Cell function tests ^[Flex C]

Analyte (measurand)	Test material (matrix)	Test technique
Release of IFN- γ after stimulation with antigens (Aspergillus 1 / 2, Babesia microti, Bartonella henselae, Candida albicans, Chlamydia pneumoniae, Chlamydia trachomatis, cytomegalovirus, ehrlichia, anaplasma, Epstein-Barr virus, HHV6, HHV7, HSV1, HSV2, Mycoplasma pneumoniae, rickettsia, varicella zoster virus, Yersinia enterocolitica)	Li-heparin blood, acid citrate dextrose blood, citrate phosphate dextrose adenine blood, NA-heparin blood	Cytokine release, measurement of cytokines using EliSpot
Release of IFN γ , IL2 after stimulation with antigens (Aspergillus 1 / 2, Babesia microti, Bartonella henselae, Candida albicans, Chlamydia pneumoniae, Chlamydia trachomatis, ehrlichia, anaplasma, HHV6, HHV7, HSV1, HSV2, Mycoplasma pneumoniae, rickettsia, SARS-CoV-2, varicella zoster virus, Yersinia enterocolitica)	Li-heparin blood, acid citrate dextrose blood, citrate phosphate dextrose adenine blood, NA-heparin blood	Cytokine release, measurement of cytokines using iSpot

Medical laboratory field: Microbiology

Type of examination:

Ligand assays ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Borrelia IgG, IgM	Serum	ELISA
Borrelia IgG, IgM	Serum	Dot blot
Borrelia IgG, IgM	Serum	Line blot
Campylobacter jejuni IgG, IgA	Serum	Immunoblot
Chlamydia pneumoniae IgG, IgA	Serum	ELISA
Chlamydia trachomatis IgG, IgA	Serum	ELISA
Echinococcus IgG	Serum	EIA
Entamoeba histolytica IgG	Serum	EIA
Leishmania IgG	Serum	EIA
Mycoplasma pneumoniae IgG, IgA	Serum	ELISA
Taenia solium IgG	Serum	EIA
Toxocara canis IgG	Serum	EIA
Toxoplasma gondii IgM, IgG	Serum	ELISA
Trichinella spiralis IgG	Serum	EIA
Yersinia enterocolitica IgG, IgA	Serum	ELISA

Type of examination:

Microscopy ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Anaplasma phagocytophilum IgG, IgM	Serum	Immunofluorescence test
Babesia IgG, IgM	Serum	Immunofluorescence test
Bartonella henselae, B. quintana IgG, IgM	Serum	Immunofluorescence test
Ehrlichia chaffeensis IgG, IgM	Serum	Immunofluorescence test
Rickettsia typhi, Rickettsia IgG, IgM	Serum	Immunofluorescence test

Medical laboratory field: Virology

Type of examination:

Ligand assays ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Cytomegalovirus IgG, IgM	Serum	ELISA
Echovirus IgG, IgA	Serum	ELISA
Epstein-Barr virus IgG, IgM	Serum	Dot blot
Herpes simplex viruses IgG, IgA, IgM	Serum	ELISA
Parvovirus B19 IgG, IgM	Serum	ELISA
SARS-CoV-2 virus IgG, IgA	Serum	ELISA
Varicella zoster virus IgG, IgA, IgM	Serum	ELISA

Type of examination:

Microscopy ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Coxsackie virus IgG, IgA	Serum	Immunofluorescence test