

## 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

**ArminLabs GmbH**  
**Zirbelstraße 58, 86154 Augsburg**

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

**Types of examinations:**  
Flow cytometry, Ligand assays, Cell function tests

**Materials:**  
as mentioned in the annex of the Accreditation Certificate

The accreditation certificate shall only apply in connection with the notice of accreditation of 01.03.2017 with the accreditation number D-ML-20488-01 and is valid until 28.02.2022. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 3 pages.

Registration number of the certificate: **D-ML-20488-01-00**

Frankfurt am Main,  
01.03.2017

Uwe Zimmermann  
Head of Division

Translation issued:  
20.03.2017

  
Head of Division

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

See notes overleaf.

# Deutsche Akkreditierungsstelle GmbH

Office Berlin  
Spittelmarkt 10  
10117 Berlin

Office Frankfurt am Main  
Europa-Allee 52  
60327 Frankfurt am Main

Office Braunschweig  
Bundesallee 100  
38116 Braunschweig

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.

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). 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](http://www.european-accreditation.org)

ILAC: [www.ilac.org](http://www.ilac.org)

IAF: [www.iaf.nu](http://www.iaf.nu)



Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-20488-01-00  
according to DIN EN ISO 15189:2014

Period of validity: 01.03.2017 to 28.02.2022

Date of issue: 01.03.2017

Holder of certificate:

**ArminLabs GmbH**  
**Zirbelstraße 58, 86154 Augsburg**

**Examinations in the field:**

Medical laboratory diagnostics

**Medical laboratory fields:**

Immunology

Microbiology

Virology

**Types of examinations:**

Flow cytometry

Ligand assays

Cell function tests

Within the given examination field marked with \*, the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following: the free choice of standards or equivalent examination procedures. The listed examination procedures are exemplary. The medical laboratory maintains a current list of all examination procedures within the flexible scope of accreditation.

## Medical laboratory field: Immunology

### Type of examination:

#### Flow cytometry

Analyte (measured parameter)	Test material (matrix)	Test method
Immune status	EDTA-, heparin-, CPDA-blood	Flow cytometry

### Type of examination:

#### Cell function tests

Analyte (measured parameter)	Test material (matrix)	Test method
T-lymphocytes with ehrlichia	CPDA-blood, heparin-blood	Elispot
T-lymphocytes with yersinia	CPDA-blood, heparin-blood	Elispot
T-lymphocytes with Chlamydia pneumoniae	CPDA-blood, heparin-blood	Elispot
T-lymphocytes with Chlamidia trachomatis	CPDA-blood, heparin-blood	Elispot
T-lymphocytes with CMV	CPDA-blood, heparin-blood	Elispot
T-lymphocytes with EBV	CPDA-blood, heparin-blood	Elispot
T-lymphocytes with HSV1/HSV2	CPDA-blood, heparin-blood	Elispot

## Medical laboratory field: Microbiology

### Type of examination:

#### Ligand assays\*

Analyte (measured parameter)	Test material (matrix)	Test method
Toxoplasmosis IgM, IgG	Serum, EDTA-, heparin-, citrate-plasma	EIA
Chlamydia pneumoniae IgG, IgA	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Chlamydia trachomatis IgG, IgA	Serum, EDT-, heparin-, citrate-plasma	ELISA
Mycoplasma pneumoniae IgG, IgA, IgM	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Yersinia enterocolitica IgA, IgG	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Borrelia IgG, IgM	Serum, EDTA-, heparin-, citrate-plasma	Microarray
Borrelia IgG, IgM	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Borrelia IgG, IgM	Serum, EDTA-, heparin-, citrate-plasma	Line-Blot
Babesia IgG	Serum	IFT
Rickettsia typhi, Rickettsia IgG	Serum	IFT
Anaplasma IgG	Serum	IFT
Bartonella henselae IgG	Serum	IFT
Bartonella quintana IgG	Serum	IFT
Anaplasma IgM	Serum	IFT

## Medical laboratory field: Virology

### Type of examination:

#### Ligand assays\*

Analyte (measured parameter)	Test material (matrix)	Test method
Herpes simplex Virus1-2 IgM, IgG	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Varizellen Zoster Virus IgM, IgA	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Varizellen Zoster Virus IgG	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Cytomegalie-Virus IgG, IgM	Serum, EDTA-, heparin-, citrate-plasma	ELISA
Epstein-Barr-Virus CA IgG, IgM, EBNA, Early-Antigen und Avidität	Serum, EDTA-, heparin-, citrate-plasma	IFT
HHV6 IgG und IgM	Serum, EDTA-, heparin-, citrate-plasma	IFT
Coxsackie-Virus IgG	Serum, EDTA-, heparin-, citrate-plasma	IFT
Coxsackie-Virus IgA	Serum, EDTA-, heparin-, citrate-plasma	IFT