Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-ML-22296-01-00 according to DIN EN ISO 15189:2014

Valid from: 02.12.2022
Date of issue: 02.12.2022

Certificate holder:

MVZ für Integrative Diagnostik & Medizin GmbH
Zirbelstraße 58, 86154 Augsburg

Examinations in the field:

Medical Laboratory Diagnostics
The medical laboratory meets the minimal requirements of DIN EN ISO 15189:2014 and, if applicable, additional legal and normative requirements, including those in relevant sectoral schemes, in order to carry out the conformity assessment activities listed below.
The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories and confirm generally with the principles of DIN EN ISO 9001.

Medical laboratory fields:
Clinical chemistry
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. 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 modification, development and refinement of 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.

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.

Medical laboratory field: Clinical Chemistry

Type of test:
Ligand assays*

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

Medical laboratory fields: Immunology

Type of test:
Flow cytometry**

Analyte (measurement parameter)	Test material (matrix)	Test technique
Immune status	EDTA, heparin blood	Flow cytometry

Medical laboratory field: Microbiology

Type of test:
Ligand assays*

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

Type of test:
Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Babesia IgG, IgM	Serum	IFT
Rickettsia typhi, Rickettsia IgG, IgM	Serum	IFT

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anaplasma phagocytophilum IgG, IgM	Serum	IFT
Bartonella henselae, B. quintana IgG, IgM	Serum	IFT
Ehrlichia chaffeensis IgG, IgM	Serum	IFT

Type of test:
Cell function tests**

Analyte (measurement parameter)	Test material (matrix)	Test technique
release of IFNg after stimulation with antigens (Bartonella henselae) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Babesia microti) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Mycoplasma pneumoniae) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (ehrlichia / anaplasma) (ELISPot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Chlamydia pneumoniae) (ELISPot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Chlamydia trachomatis) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Yersinia) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (rickettsiae) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Aspergillus 1 / 2) (ELISPot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Candida albicans) (ELISPot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA

Medical laboratory field: Virology

Type of test:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Varicella zoster virus IgG, IgA, IgM	Serum	ELISA
Parvovirus B19 IgG, IgM	Serum	ELISA
Cytomegalovirus IgG, IgM	Serum	ELISA
Herpes simplex viruses IgG, IgA, IgM	Serum	ELISA
FSME virus IgG, IgM	Serum	ELISA
Enterovirus IgG, IgA	Serum	ELISA
Epstein-Barr virus IgG, IgM	Serum	Immunoarray
Anti-SARS-CoV-2 IgG, IgA	Serum	ELISA

Type of test:
Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Coxsackie virus A7/B1 IgG, IgA	Serum	IFT
Echoviruses type 7 IgG, IgA	Serum	IFT
HHV-6 IgG, IgM	Serum	IFT
HHV-7 IgG	Serum	IFT
HHV-8 IgG	Serum	IFT

Type of test:
Cell function tests**

Analyte (measurement parameter)	Test material (matrix)	Test technique
release of IFNg after stimulation with antigens (Epstein-Barr virus) (ELISPot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (cytomegalovirus) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (HSV-1 / HSV-2) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (Varicella zoster virus) (ELISPot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (HHV-6) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens(HHV-7) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA
release of IFNg after stimulation with antigens (SARS-CoV-2) (ELISpot)	Li-heparin blood, ACD blood, CPDA blood, Na-heparin blood	release of cytokin, measurement cytocin with IGRA

Type of test:
Molecular biological tests (amplification procedures)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
SARS-CoV-2	Nasopharyngeal swab, bronchoalveolar lavage, throat swab	Real-time PCR