

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-18406-01-00 accordance with DIN EN ISO 15189:2014

Period of validity: 23.08.2016 to 13.10.2018

Date of issue: 23.08.2016

Holder of certificate:

BCA-clinic Betriebs GmbH & Co.KG
BCA-lab
Morellstr.33, 86159 Augsburg

Examinations in the fields:

Medical Laboratory Diagnostics

Examinations areas:

Immunology
Microbiology
Virology

Examination procedures of:

Flow cytometry
Ligand assay
Cell function testing

Within the given examination procedures marked with **, the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following:
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.

Examination area: Immunology

Examination procedures: Flow Cytometry

Analyt (Measurand)	Test material (Matrix)	Technique of examination
Immune status	EDTA-, heparin-blood	Flow cytometry

Examination area: Microbiology

Examination procedures: Ligand Assays**

Analyt (Measurand)	Test material (Matrix)	Technique of examination
Toxoplasmosis IgM, IgG	serum, EDTA-,heparin-,citrate-plasma	ELISA
Chlamydia pneumoniae IgG, IgA,	serum, EDTA-,heparin-,citrate-plasma	ELISA
Chlamydia trachomatis IgG, IgA	serum, EDTA-,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
Lyme disease IgG, IgM	serum, EDTA-,heparin-,citrate-plasma	ELISA
Lyme disease IgG, IgM	serum, EDTA-,heparin-,citrate-plasma	Line Blot
Babesia microti IgG	serum	IFT
Rickettsia typhi IgG	serum	IFT
Rickettsia rickettsii IgG	serum	IFT
Anaplasma IgG	serum	IFT
Bartonella henselae IgG	serum	IFT
Bartonella quintana IgG	serum	IFT

Examination procedures: Cell Function Testing

Analyt (Measurand)	Test material (Matrix)	Technique of examination
T-lymphocytes with Ehrlichia LTT	heparin-blood	Elispot
T-lymphocytes with Yersinia LTT	heparin-blood	Elispot
T-lymphocytes with Chlamydia pneumoniae LTT	heparin-blood	Elispot
T-lymphocytes with Chlamydia trachomatis LTT	heparin-blood	Elispot

Examination area: Virology

Examination procedures: Ligand Assays

Analyt (Measurand)	Testing material (Matrix)	Technique of examination
Herpes simplex Virus1-2 IgM, IgG	serum, EDTA-,heparin-,citrate-plasma	ELISA
Cytomegalo-Virus IgG, IgM	serum, EDTA-,heparin-,citrate-plasma	ELISA
Epstein-Barr-Virus CA IgG, IgM	serum, EDTA-,heparin-,citrate-plasma	ELISA
Epstein-Barr-Virus EBNA-1 IgG	serum, EDTA-,heparin-,citrate-plasma	ELISA

Examination procedures: Cell Function Testing

Analyt (Measurand)	Testing material (Matrix)	Technique of examination
T-lymphocytes with Epstein-Barr-Virus LTT	heparin-blood	Elispot
T-lymphocytes with Cytomegalo-Virus LTT	heparin-blood	Elispot