

Deutsche Akkreditierungsstelle GmbH

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

Period of validity: 16.06.2016 to 13.10.2018

Date of issue: 16.06.2016

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

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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 Borrelia LTT | heparin-blood | Elispot |
| 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 |