

# 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                  |