

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-21360-01-00 according to DIN EN ISO IEC 17025:2018

Valid from: 04.10.2019

Date of issue: 12.09.2019

Holder of certificate:

CheckImmune GmbH
Campus Virchow Klinikum, Cranach Haus
Augustenburger Platz 1, 13353 Berlin

Tests in the field:

Health care (Medical laboratory examinations within clinical trials)

Analytical Field:

Immunology

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

Within the given testing field marked with **, the testing laboratory is permitted without being required to inform and obtain prior approval from DAkkS the modification, development and refinement of test methods.

The listed test methods are exemplary.

The testing laboratory maintains a current list of all test methods in a flexible scope of accreditation.

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.

<https://www.dakks.de/en/content/accredited-bodies-dakks>

Analytical Field: Immunology

Type of test:

Flow cytometry**

Analyte (Parameter)	Specimen	Method
Leucocyte count	EDTA-Blood, BCT-Blood	Flow cytometry
Immune status	EDTA-Blood, BCT-Blood	Flow cytometry (Characterisation of hemapoetic cells)
Receptor occupancy	EDTA-Blood, BCT-Blood	Flow cytometry
HLA-DR	EDTA-Blood, BCT-Blood	Flow cytometry

Type of test:

Ligand assays**

Analyte (Parameter)	Specimen	Method
Anti-drug antibodies (ADA)	Plasma, Serum	ELISA
Human-Anti-Mouse-Antibody (HAMA; Screening and Confirmation Assay)	Plasma, Serum	ELISA
sE-Selectin	Serum, Plasma	ELISA
April (A Proliferation-Inducing Ligand)	Serum, Plasma	ELISA
IL-28A	Serum, Plasma	ELISA
IL-27	Serum, Plasma	ELISA
IL-18	Serum, Plasma	ELISA
BAFF	Serum, Plasma	ELISA
IL12p40	Serum, Plasma	Electro-chemiluminescence immunoassay
IL-17	Serum, Plasma	Electro-chemiluminescence immunoassay
TNF α	Serum, Plasma	Elektro-chemiluminescence immunoassay
TNF- α , IFN- γ , IL-6 and IL-10 (4-Plex MSD)	Serum, Plasma	Electro-chemiluminescence immunoassay
TNF, IFN γ , IL-2, IL-4 and IL-10 (5-Plex-MSD)	Serum, Plasma	Electro-chemiluminescence immunoassay
IFN- γ , IL-1 β , IL-2, IL-4, IL-6, IL-8, IL-10, IL-12p70, IL-13, TNF α (10-Plex-MSD)	Serum, Plasma	Electro-chemiluminescence immunoassay
TGF β 1	Serum, Plasma	Fluorescence assay
IFN- α , IFN- γ , IL-2, IL-4, IL-5, IL-10, IL-6, IL-1 β , IL-15, IL17A, IL-8, IP-10, EGF, CCL2 (MCP-1), CCL3 (MIP-1 α), CCL5 (RANTES), CCL7 (MCP-3), CX3CL1	Serum, Plasma	Fluorescence assay

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Analyte (Parameter)	Specimen	Method
IL-21, IL-23, MCP-2, BCA-1, TARC	Serum, Plasma	Fluorescence assay
CXCL 11, CXCL9, MIP-3 β (CCL19)	Serum, Plasma	Fluorescence assay

Type of test:

Functional cell testing**

Analyte (Parameter)	Specimen	Method
TNF- α , IL-6, IL-10 and IFN- γ (after IL-1 β -Stimulation 24h)	Li-Heparin blood	In vitro stimulation
TNF- α , IL-6, IL-10 and IFN- γ (after LPS-Stimulation 24h)	Li-Heparin blood	In vitro stimulation
IFN γ , TNF α , IL-2, IL-4, IL-5, IL10 (after ConA-Stimulation 24h)	Li-Heparin blood	In vitro stimulation
IFN γ , TNF α , IL-2, IL-4, IL-5, IL10, IL-17 (after SEB-Stimulation 24h)	Li-Heparin blood	In vitro stimulation