

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-22411-01-00 according to DIN EN ISO 15189:2014

Valid from: 06.02.2024

Date of issue: 06.02.2024

Holder of accreditation certificate:

DKMS Life Science Lab gGmbH
St. Petersburger Straße 2, 01069 Dresden

with the location

DKMS Life Science Lab gGmbH
St. Petersburger Straße 2, 01069 Dresden

The medical laboratory meets the requirements of DIN EN ISO 15189:2014 to carry out the conformity assessment activities listed in this annex. The medical laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories and they conform to the principles of DIN EN ISO 9001.

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>.

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

Annex to the accreditation certificate D-ML-22411-01-00

Examinations in the field:

Medical Laboratory Diagnostics

Medical laboratory fields:

Virology

Transfusion medicine

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

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Medical laboratory field: Transfusion medicine

Type of examination

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
antibodies HLA-class I and II	blood, serum, plasma	Bead-Based Multiplex-Antibody-Assay

Type of examination

Lysis reaktionen**

Analyte (measurement parameter)	Test material (matrix)	Test technique
crossmatching using lymphocytes (for HLA class I and II)	blood, serum, plasma	Lymphocytotoxicity test

Type of examination

Molecular biological tests (amplification procedures)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA-class I and II (HLA-A, -B, -C, -E, -DRB1, -DQB1, -DPB1, -DRB3/4/5, -DQA1, -DPA1)	buccal swab, blood, DNA	NGS based on amplicon PCR
KIR	buccal swab, blood, DNA	NGS based on amplicon PCR
MICA, MICB, CCR5Δ32	buccal swab, blood, DNA	NGS based on amplicon PCR
ABO, RhD	buccal swab, blood, DNA	NGS based on amplicon PCR
HLA-class I and II (HLA-A, -B, -C, -DRB1, -DQB1, -DPB1)	buccal swab, blood, DNA	NGS based on long-range PCR
HLA-class I and II (HLA-A, -B, -C, -DRB1, -DQB1, -DPB1, -DRB3/4/5, -DQA1, -DPA1)	buccal swab, blood, DNA	NGS based on long-range PCR
HLA-class I and II (HLA-A, -B, -C, -DRB1, -DQB1, -DPB1, -DRB3/4/5, -DQA1, -DPA1)	buccal swab, blood, DNA	reverse SSO (PCR)
HLA-B*27, HLA-B*51, further HLA loci	buccal swab, blood, DNA	reverse SSO (PCR)

Medical laboratory field: Virology

Type of examination

Ligand assay**

Analyte (measurement parameter)	Test material (matrix)	Test technique
CMV-IgG-antibodies	buccal swab	Enzyme-Linked Immunosorbent Assay (ELISA)