

Deutsche Akkreditierungsstelle GmbH

Anlage zur Akkreditierungsurkunde D-ML-13168-09-01 nach DIN EN ISO 15189:2014

Gültig ab: 28.07.2022

Ausstellungsdatum: 28.07.2022

Urkundeninhaber:

**Medizinische Hochschule Hannover
Institut für Transfusionsmedizin und Transplantat Engineering
30625 Hannover, Carl-Neuberg-Str. 1**

Untersuchungen im Bereich:

Medizinische Laboratoriumsdiagnostik

Untersuchungsgebiet:

Transfusionsmedizin (Immungenetik und Transplantationsimmunologie gemäß Standards der European Federation for Immunogenetics (EFI), Version 8.0)

Die Anforderungen an das Managementsystem in der DIN EN ISO 15189 sind in einer für Medizinische Laboratorien relevanten Sprache verfasst und stehen insgesamt in Übereinstimmung mit den Prinzipien der DIN EN ISO 9001.

Die Urkunde samt Urkundenanlage gibt den Stand zum Zeitpunkt des Ausstellungsdatums wieder. Der jeweils aktuelle Stand des Geltungsbereiches der Akkreditierung ist der Datenbank akkreditierter Stellen der Deutschen Akkreditierungsstelle GmbH (DAkkS) zu entnehmen. <https://www.dakks.de/content/datenbank-akkreditierter-stellen>

Untersuchungsgebiet: Transfusionsmedizin
(Transfusionsmedizin (Immungenetik und Transplantationsimmunologie gemäß Standards der European Federation for Immunogenetics (EFI), Version 8.0)

ACCREDITATION CATEGORIES

| | Approved by EFI-Commissioner | |
|---|---|--|
| Renal and/or Pancreatic transplantation: | | |
| Recipient typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Antibody screening | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Antibody identification | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Donor typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Cross-matching | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Other solid organ transplantation: | | |
| Recipient typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Antibody screening | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Antibody identification | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Donor typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Cross-matching | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Haematopoietic stem cell transplantation (HSCT): | | |
| Donor registry typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Related transplantation | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Unrelated transplantation | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Cord Blood typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Cross-matching | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Chimaerism and engraftment monitoring | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Disease association studies | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Transfusion | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| HNA typing | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| HPA typing | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| HNA antibodies | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

| | | |
|-----------------------|---|-----------------------------|
| | Approved by EFI-Commissioner | |
| HPA antibodies | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |

ACCREDITATION TECHNIQUES TYPING

| | | |
|----------------------------|---|--|
| | Approved by EFI-Commissioner | |
| Class I typing by: | | |
| CDC | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Flow cytometry (HLA-B27) | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| DNA low resolution | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| DNA high resolution | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| PCR-SSP | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| PCR-SSO | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| PCR-SBT | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| NGS | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| | | |
| Class II typing by: | | |
| CDC | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| DNA low resolution | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| DNA high resolution | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| PCR-SSP | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| PCR-SSO | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| PCR-SBT | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| NGS | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |

| | | |
|-------------------------------|---|-----------------------------|
| MICA Typing: (PCR SSO) | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| KIR Typing: (PCR SSP) | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |

ACCREDITATION TECHNIQUES ANTIBODIES

HLA Antibody testing by:

CDC

Flow cytometry

ELISA

Bead array

Antibody identification by:

CDC

Flow cytometry

ELISA

Bead array

Antibody cross-matching by:

CDC

Flow cytometry

ELISA

Bead array *

| Approved by EFI-Commissioner | |
|---|--|
| | |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| | |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| | |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> |

*Remark: "Only for HLA Class I"