

Deutsche Akkreditierungsstelle GmbH

Anlage zur Akkreditierungsurkunde D-ML-17347-01-01 nach DIN EN ISO 15189:2014

Gültig ab: 16.06.2022

Ausstellungsdatum: 16.06.2022

Urkundeninhaber:

**Institut für Klinische Transfusionsmedizin und Immungenetik Ulm gemeinnützige
GmbH (IKT)
Helmholtzstraße 10, 89081 Ulm**

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

(Immungenetik und Transplantationsimmunologie gemäß Standards der European Federation of Immungentics (EFI), Version 8.0)

ACCREDITATION CATEGORIES

	Approved by EFI-Commissioner	
Renal and/or Pancreatic transplantation:		
Recipient typing	Yes <input type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>
Cross-matching	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Other solid organ transplantation:		
Recipient typing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Antibody screening	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Antibody identification	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Donor typing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Cross-matching	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Haematopoietic stem cell transplantation (HSCT):		
Donor registry typing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Related transplantaton	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Unrelated transplantaton	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"/>

	Approved by EFI-Commissioner	
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 type="checkbox"/>	No <input checked="" type="checkbox"/>
HNA antibodies *	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 checked="" type="checkbox"/>	No <input 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 type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>
PCR-SSO	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
PCR-SBT	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

	Approved by EFI-Commissioner	
NGS	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
MICA Typing:	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
KIR Typing:	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

ACCREDITATION TECHNIQUES ANTIBODIES

	Approved by EFI-Commissioner	
Antibody testing by:		
CDC	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Flow cytometry	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
ELISA	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Bead array	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Antibody identification by:		
CDC	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Flow cytometry	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
ELISA	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Bead array	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Antibody cross-matching by:		
CDC	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Flow cytometry	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
ELISA	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Bead array	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
HNA antibodies: *	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
HPA antibodies: *	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

* Subcontract: 04-DE-063.937 Mannheim