

Deutsche Akkreditierungsstelle GmbH

Anlage zur Akkreditierungsurkunde D-ML-14569-01-02 nach DIN EN ISO 15189:2014

Gültig ab: 12.11.2020

Ausstellungsdatum: 12.11.2020

Urkundeninhaber:

**Städtisches Klinikum Braunschweig gGmbH
Institut für Klinische Transfusionsmedizin
Celler Straße 38, 38114 Braunschweig**

Untersuchungen im Bereich:

Medizinische Laboratoriumsdiagnostik

Untersuchungsgebiet:

Transfusionsmedizin (Immungenetik und Transplantationsimmunologie gemäß Standards der European Federation for Immunogenetics (EFI), Version 7.0)

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 for Immunogenetics (EFI), Version 7.0)

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 type="checkbox"/>	No <input checked="" type="checkbox"/>
Antibody identification	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Donor typing (living type)	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 (cornea only)	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 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 type="checkbox"/>	No <input checked="" type="checkbox"/>
Cross-matching	Yes <input type="checkbox"/>	No <input checked="" 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"/>
HPA antibodies	Yes <input type="checkbox"/>	No <input checked="" 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 type="checkbox"/> *	No <input type="checkbox"/>
PCR-SSP	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PCR-SSO	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
PCR-SBT	Yes <input type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>	No <input type="checkbox"/>
PCR-SBT	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
NGS	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

Anlage zur Akkreditierungsurkunde D-ML-14569-01-02

MICA Typing:

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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KIR Typing:

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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*Subcontract EFI Nr. 04-DE-003.997 - Münster

ACCREDITATION TECHNIQUES ANTIBODIES

		Approved by EFI-Commissioner	
Antibody testing by:			
CDC	Yes <input type="checkbox"/>	No <input checked="" 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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
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 type="checkbox"/>	No <input checked="" type="checkbox"/>
HPA antibodies:		Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>