

Deutsche Akkreditierungsstelle GmbH

Anlage zur Akkreditierungsurkunde D-ML-17345-01-01 nach DIN EN ISO 15189:2014

Gültig ab: 19.07.2022

Ausstellungsdatum: 19.07.2022

Urkundeninhaber:

DRK Blutspendedienst Baden-Württemberg-Hessen gemeinnützige GmbH

Standorte:

Institut für Transfusionsmedizin und Immunhämatologie Frankfurt am Main

Sandhofstraße 1, 60528 Frankfurt am Main

Institut für Transfusionsmedizin und Immunologie Mannheim

Friedrich-Ebert-Str. 107, 68167 Mannheim

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>

Standort Frankfurt am Main

Untersuchungsgebiet: 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 (living type)	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 (cornea only)	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 type="checkbox"/>	No <input checked="" 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 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 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 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"/>	
MICA typing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
KIR typing	Yes <input type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>	No <input 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"/>
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 type="checkbox"/>	No <input checked="" type="checkbox"/>

Standort Mannheim

Untersuchungsgebiet: 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 (only living donors)	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Cross-matching (only living donors)	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 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"/>
Haematopoietic stem cell transplantation (HSCT):		
Donor registry typing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Related donor typing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Unrelated donor typing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Cord Blood typing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Cross-matching (only with T-cells)	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

Transfusion

Approved by EFI-Commissioner	
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
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 checked="" type="checkbox"/>	No <input type="checkbox"/>	
PCR-SBT	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
NGS	Yes <input type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>	No <input type="checkbox"/>	
NGS	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
MICA typing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
KIR typing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
HNA typing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
HPA 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"/>
Cross-matching by:		
CDC (only with T-cells)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
Flow cytometry	Yes <input checked="" type="checkbox"/>	No <input 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"/>