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Annex to the Accreditation Certificate D-ML-13374-01-00 according to DIN EN ISO 15189:2024

Valid from: 29.01.2025
Date of issue: 29.01.2025

Holder of certificate:

Medizinisches Laboratorium Dr. med. Bernhard Thiele
Im Institut für Immunologie und Genetik
Pfaffplatz 10, 67655 Kaiserslautern

with the location

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Pfaffplatz 10, 67655 Kaiserslautern

The medical laboratory meets the requirements of DIN EN ISO 15189:2024 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 confirm generally with the principles of DIN EN ISO 9001.

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

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 http://www.dakks.de.

Test in the field:

Medical Laboratory Diagnostics

Test areas:

Human genetics (molecular human genetics)
Human genetics (cytogenetics)
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 test methods are exemplary. The medical laboratory maintains a current list of all test methods in a flexible scope of accreditation.
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Test area: Human genetics (molecular human genetics)

Type of test:
Molecular biological tests (amplification procedures)**

Analyte (measurement parameter)	Test material (matrix) (input material; test material)	Test technique
SNV-genotyping (detection of specific variant alleles)		
Antithrombin III deficiency (SERPINC1 gene [OMIM *107300])	EDTA blood, DNA; DNA	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS) (Illumina MiSeq, NextSeq), GATK
HIV host resistance Chemokine receptor 5 (CCR5)-delta 32 deletion	EDTA blood, DNA; DNA	PCR, gel electrophoresis
Meulengracht (Gilbert) syndrome (Customized Panel ABA) (UGT1A1*28-, *6- polymorphism)	EDTA blood, EDTA bone marrow; DNA	multiplex PCR, Matrix-assisted laser desorption ionization with time-of-flight mass spectrometer detection (MALDI-TOF-MS)
Protein C deficiency (PROC gene [OMIM *612283])	EDTA blood, DNA; DNA	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS) (Illumina MiSeq, NextSeq), GATK
Protein S deficiency (PROS1 gene [OMIM *176880])	EDTA blood, DNA; DNA	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS) (Illumina MiSeq, NextSeq), GATK
Von Willebrand syndrome (VWF gene [OMIM *613160])	EDTA blood, DNA; DNA	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS) (Illumina MiSeq, NextSeq), GATK
TP53 (TP53 gene)	EDTA blood, DNA; DNA	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS) (Illumina MiSeq, NextSeq), GATK

Analyte (measurement parameter)	Test material (matrix) (input material; test material)	Test technique
5-Fluorouracil-Toxicity-Panel (DPYD (OMIM *612779), dbSNP rs3918290, rs55886062, rs56038477, rs67376798, rs72549309, and rs75017182)	EDTA blood, DNA; DNA	multiplex PCR, Matrix-assisted laser desorption ionization with time-of-flight mass spectrometer detection (MALDI-TOF-MS)
AML-Panel (detection of 55 mutations in the genes DNMT3A, FLT3, IDH1, IDH2, KIT, and NPM1)	EDTA blood, DNA; DNA	multiplex PCR, Matrix-assisted laser desorption ionization with time-of-flight mass spectrometer detection (MALDI-TOF-MS)
Thrombophilia-Panel (AT3 [OMIM *107300] dbSNP rs121909548; F2 [OMIM *176930] dbSNP rs3136516, rs1799963; F5 [OMIM*612309] dbSNP rs6025; F12 [OMIM*610619] dbSNP rs1801020; F13 [OMIM*134570] dbSNP rs5985; FSAP [OMIM*603924] dbSNP rs7080536; MTHFR [OMIM*607093] dbSNP rs1801133, rs1801131; PAI-1 [OMIM*173360] dbSNP rs2227631, rs587776796)	EDTA blood, DNA; DNA	multiplex PCR, Matrix-assisted laser desorption ionization with time-of-flight mass spectrometer detection (MALDI-TOF-MS)
Detection of specific chromosomal regions		
AF4/MLL translocation t(4;11)	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis
cABL/BCR translocation t(9;22), qualitative	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis
cABL/BCR translocation t(9;22), quantitative	peripheral blood, bone marrow; RNA	Realtime-PCR
CCND1/IGH translocation t(11;14))	peripheral blood, bone marrow; DNA	PCR, gel electrophoresis
FIP1L1-PDGFRA fusion del(4)(q12q12)	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis
IGH/BCL2 translocation t(14;18))	peripheral blood, bone marrow; DNA	PCR, gel electrophoresis
MYH11/CBFB translocation inv(16))	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis
PBX1/E2A translocation t(1;19)	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis
PML/RARA translocation t(15;17)	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis

Analyte (measurement parameter)	Test material (matrix) (input material; test material)	Test technique
RUNX1/RUNX1T1 translocation t(8;21)	peripheral blood, bone marrow; RNA	PCR, gel electrophoresis
Fragment length analysis		
Chimerism analysis	peripheral blood, bone marrow, buccal swab; DNA	Genotype for chimerism investigation using STR analysis
Targeted copy number analysis		
Hereditary breast/ovarian cancer (HBOC) Suspected increased hereditary risk after positive family history. (BRCA1 [OMIM *113705], BRCA2 [OMIM *600185])	EDTA blood, DNA; DNA	MLPA
HNPCC/Lynch syndrome (MLH1 [OMIM *120436] , MSH2 [OMIM *609309] , MSH6 [OMIM *600678] , PMS2 [OMIM *600259], EPCAM [OMIM *185535])	EDTA blood, DNA; DNA	MLPA
Marfan syndrome (FBN1 gene [OMIM *134797])	EDTA blood, DNA; DNA	MLPA
Antithrombin III deficiency (SERPINC1 gene [OMIM *107300])	EDTA blood, DNA; DNA	MLPA
Protein C deficiency (PROC gene [OMIM *612283])	EDTA blood, DNA; DNA	MLPA
Protein S deficiency (PROS1 gene [OMIM *176880])	EDTA blood, DNA; DNA	MLPA
Von-Willebrand syndrome (VWF gene [OMIM *613160])	EDTA blood, DNA; DNA	MLPA
Cystic fibrosis (CFTR gene [OMIM *602421])	EDTA blood, DNA; DNA	MLPA

Analyte (measurement parameter)	Test material (matrix) (input material; test material)	Test technique
Targeted NGS panel analysis for named suspected clinical diagnoses		
Hereditary breast/ovarian carcinoma (HBOC) (BRCA1 [OMIM *113705], BRCA2 [OMIM *600185], CHEK2 [OMIM +604373], PALB2 [OMIM *610355], RAD51C [OMIM *602774], ATM [OMIM *607585], BRIP1 [OMIM *605882], CDH1 [OMIM *192090], EPCAM [OMIM *185535], MLH1 [OMIM *120436], MSH2 [OMIM *609309], MSH6 [OMIM *600678], PMS2 [OMIM *600259], PTEN [OMIM *601728], RAD51D [OMIM *602954], STK11 [OMIM *602216], TP53 [OMIM *191170])	EDTA blood, DNA; DNA	Sequence capture (Illumina), Sequencing-by-synthesis (Illumina), MiSeq, NextSeq (Illumina), GATK (SNV), CNV-GATK (CNV)
Breast/ovarian carcinoma; prostate carcinoma; pancreatic carcinoma progressed ovarian cancer, metastatic and HER2-negative breast cancer, metastatic pancreatic cancer after platinum-based chemotherapy, metastatic, castration-resistant prostate cancer for treatment decisions (PARP inhibitors) (BRCA1 [OMIM *113705], BRCA2 [OMIM *600185])	EDTA blood, DNA; DNA	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS) (Illumina MiSeq, NextSeq), GATK

Analyte (measurement parameter)	Test material (matrix) (input material; test material)	Test technique
Breast/ovarian carcinoma 1. recurrence of ovarian cancer for treatment decision (PARP inhibitors) 2. HER2-negative primary metastatic breast cancer for treatment decision (PARP inhibitors) (BRCA1 [OMIM *113705], BRCA2 [OMIM *600185])	Tissue samples, DNA; DNA	amplicon-based sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS), MiSeq, NextSeq (Illumina), GATK
HNPCC/Lynch syndrome (MLH1 [OMIM *120436], MSH2 [OMIM *609309], MSH6 [OMIM *600678], PMS2 [OMIM *600259], EPCAM [OMIM *185535])	EDTA blood, DNA; DNA	Sequence capture (Illumina), Sequencing-by-synthesis (Illumina), MiSeq, NextSeq (Illumina), GATK
Marfan syndrome (FBN1 gene [OMIM *134797])	EDTA blood, DNA; DNA	Sequence capture (Illumina), Sequencing-by-synthesis (Illumina), MiSeq, NextSeq (Illumina), GATK (SNV), CNV-GATK (CNV)
Cystic fibrosis (CFTR gene [OMIM *602421])	EDTA blood, DNA; DNA	Sequence capture (Illumina), Sequencing-by-synthesis (Illumina), MiSeq, NextSeq (Illumina), GATK (SNV), CNV-GATK (CNV)
Developmental disorders (Whole exome sequencing (WES); SNV, CNV) (Gene panel with 978 genes)	EDTA blood, DNA; DNA	Sequence capture (Twist), Sequencing-by-synthesis (Illumina), NextSeq (Illumina), Congenica (SNV), CNV-GATK (CNV)

Analyte (measurement parameter)	Test material (matrix) (input material; test material)	Test technique
Dilated cardiomyopathy (DCM) (Whole exome sequencing (WES); SNV, CNV) (ACTC1 [OMIM *102540], ACTN2 [OMIM *102573], ANKRD1 [OMIM *609599], BAG3 [OMIM *603883], CSRP3 [OMIM *600824], DES [OMIM *125660], DMD [OMIM *300377], DSG2 [OMIM *125671], DSP [OMIM *125647], EMD [OMIM *300384], EYA4 [OMIM *603550], FHL1 [OMIM *300163], HFE [OMIM *613609], LDB3 [OMIM *605906], LMNA [OMIM *150330], MYBPC3 [OMIM *600958], MYH6 [OMIM *160710], MYH7 [OMIM *160760], NXN [OMIM *612895], PLN [OMIM *172405], PRDM16 [OMIM *605557], PSEN1 [OMIM *104311], PSEN2 [OMIM *600759], RBM20 [OMIM *613171], SCN5A [OMIM *600163], SGCD [OMIM *601411], TAZ [OMIM *300394], TCAP [OMIM *604488], TMPO [OMIM *188380], TNNI3 [OMIM *191044], TNNT2 [OMIM *191045], TPM1 [OMIM *191010], TTN [OMIM *188840], VCL [OMIM *193065])	EDTA blood, DNA; DNA	Sequence capture (Twist), Sequencing-by-synthesis (Illumina), NextSeq (Illumina), Congenica (SNV), CNV-GATK (CNV)
Amyloidosis (Whole exome sequencing (WES); SNV, CNV) (APOA1 [OMIM *107680], B2M [OMIM *109700], FGA [OMIM *134820], GSN [OMIM *137350], LYZ [OMIM *153450], OSMR [OMIM *601743], TTR [OMIM *176300])	EDTA blood, DNA; DNA	Sequence capture (Twist), Sequencing-by-synthesis (Illumina), NextSeq (Illumina), Congenica (SNV), CNV-GATK (CNV)

Analyte (measured variable)	Examination material (input material; test material)	Examination technique
Myelodysplastic syndrome (MDS) (ASXL1 [OMIM *612990], CBL [OMIM *165360], CSF3R [OMIM *138971], DDX41 [OMIM *608170], DNMT3A [OMIM *602769], EZH2 [OMIM *601573], FLT3 [OMIM *136351], IDH1 [OMIM *147700], IDH2 [OMIM *147650], JAK2 [OMIM *147796], KIT [OMIM *164920], NPM1 [OMIM *164040], NRAS [OMIM *164790], RUNX1 [OMIM *151385], SETBP1 [OMIM *611060], SF3B1 [OMIM *605590], SRSF2 [OMIM *600813], TET2 [OMIM *612839], TP53 [OMIM *191170], U2AF1 [OMIM *191317], ZRSR2 [OMIM *300028])	EDTA blood, DNA from blood; DNA	amplicon-based sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS), MiSeq, NextSeq (Illumina), GATK
Non targeted NGS-based analysis for undirected clinical indication		
Whole exome sequencing (WES); SNV, CNV	EDTA blood, DNA; DNA	Sequence capture (Twist), Sequencing-by-synthesis (Illumina), NextSeq (Illumina), Congenica (SNV), CNV-GATK (CNV)

Test area: Human genetics (cytogenetics)

Type of test:
Chromosome analysis**

Analyte (measurement parameter)	Test material (matrix)	Test technique
innate set of chromosomes	peripheral blood, umbilical cord blood	Chromosome banding analysis
acquired set of chromosomes	bone marrow, blood	Chromosome banding analysis
Detection of specific chromosomal regions	Native and/or cultured cells from bone marrow, amniotic fluid, chorionic villi, peripheral blood, Umbilical cord blood	Fluorescence in situ hybridization (FISH): Rapid prenatal test Detection of microdeletions, rearrangements, translocations, numerical aberrations

Test area: Virology

Type of test:
Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
anti-HAV IgG	serum, EDTA plasma	CMIA
HBs-Ag	serum, EDTA plasma	CMIA
anti-HBs quantitative	serum, EDTA plasma	CMIA
anti-HBc IgG	serum, EDTA plasma	CMIA
anti-HBe	serum, EDTA plasma	CMIA
anti-HCV	serum, EDTA plasma	CMIA
HIV1/2 Ab / p24 antigen	serum, EDTA plasma	CMIA
CMV IgG + IgM Ab	serum, EDTA plasma	CMIA
HTLV I/II Ab	serum, EDTA plasma	CMIA
Rubella-Virus IgG Ab	serum, EDTA plasma	CMIA
EBV EBNA-1 IgG	serum, EDTA plasma	CMIA
EBV VCA IgG	serum, EDTA plasma	CMIA
EBV VCA IgM	serum, EDTA plasma	CMIA

Type of test:
Molecular biological tests (amplification procedures) **

Analyte (measurement parameter)	Test material (matrix)	Test technique
HIV-RNA	serum, plasma, cerebrospinal fluid	Realtime-PCR, quantitativ
HIV-RNA or proviral DNA	serum, plasma	High-resolution resistance testing using reverse transcription, nested PCR and next generation sequencing (Illumina MiSeq), NGS-Virology-Pipeline (in-house)
HIV-RNA or proviral DNA	serum, plasma	High-resolution tropism determination using reverse transcription, nested PCR and next generation sequencing (Illumina MiSeq), NGS-Virology-Pipeline (in-house)
HBV-DNA	serum, plasma	Realtime-PCR, quantitative
HBV-DNA	serum, plasma	High-resolution resistance testing / genotyping using PCR and next generation sequencing (Illumina MiSeq), NGS-Virology-Pipeline (in-house)
HCV-RNA	serum, plasma, cerebrospinal fluid	Realtime-PCR, quantitative
HCV-RNA	serum, plasma	Genotyping using reverse transcription, PCR and sequencing
HCV-RNA	serum, plasma	High-resolution resistance testing using reverse transcription, PCR and next generation sequencing (Illumina MiSeq), NGS-Virology-Pipeline (in-house)
CMV-DNA	serum, plasma	Realtime-PCR, quantitative
HPV-DNA	Cervical swab, rinsing, urethral swab (♂), other epithelial swabs, FFPE	multiplex PCR, Matrix-assisted laser desorption ionization with time-of-flight mass spectrometer detection (MALDI-TOF-MS)

Test area:Transfusion medicine

Type of test:
Agglutination tests *

Analyte (measurement parameter)	Test material (matrix)	Test technique
AB0 system	EDTA whole blood	Ag / Ab binding gel card
Rh System	EDTA whole blood	Ag / Ab binding gel card
Kell antigen	EDTA whole blood	Ag / Ab binding gel card
free irregular antibodies (IgG)	serum/EDTA plasma	Ag / Ab binding gel card (indirect Coombstest)

Type of test:
Flow cytometry**

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA antibodies (detection and specification)	serum	Flow cytometric analysis using color-coded beads

Type of test:
Lysis reactions**

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA antibodies (crossmatch)	serum	LCT
HLA antibodies (detection and specification)	serum	LCT

Type of test:
Molecular biological examinations (amplification process)**

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA-A*, B*, C* DRB1*, DQA1*, DQB1* DPA1*, DPB1* (two field typing)	EDTA, citrate, CPDA blood, buccal swab	PCR, "large-amplicon" sequencing using next-generation sequencing (NGS) technology ("sequencing-by-synthesis", SBS)(Illumina MiSeq), NGS-HLA-Pipeline (in-house)