Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the medical laboratory

Foundation Medicine GmbH
Nonnenwald 2, Gebäude 433, 82377 Penzberg

is competent under the terms of DIN EN ISO 15189:2014 to carry out examinations in the following fields:

Medical Laboratory Diagnostics

Medical laboratory fields:
Human genetics (molecular human genetics)

The accreditation certificate shall only apply in connection with the notice of accreditation of 11.02.2021 with the accreditation number D-ML-21105-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

Registration number of the certificate: **D-ML-21105-01-00**

Frankfurt am Main,	Dipl.-Biol. Uwe Zimmermann	Translation issued:
11.02.2021J	Head of Division	11.02.2021
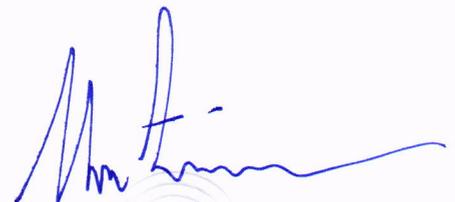
Head of Division

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

This document is a translation. The definitive version is the original German accreditation certificate.
See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-ML-21105-01-00 according to DIN EN ISO 15189:2014

Valid from: **11.02.2021**

Date of issue: 11.02.2021

Holder of certificate:

Foundation Medicine GmbH
Nonnenwald 2, Gebäude 433, 82377 Penzberg

Examinations in the field:

Medical Laboratory Diagnostics

Medical laboratory fields:

Human genetics (molecular human genetics)

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.
The listed examination procedures are exemplary. The medical laboratory maintains a current list of all examination procedures within the flexible scope of accreditation.

The management system requirements of DIN EN ISO/IEC 15189 are written in the language relevant to the operations of medical laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

Medical laboratory field: Human genetics (molecular human genetics)

Type of examination:

Molecular biological tests (amplification procedures)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Somatic gene aberrations (ABL1, ACVR1B, AKT1, AKT2, AKT3, ALK, ALOX12B, AMER1, APC, AR, ARAF, ARFRP1, ARID1A, ASXL1, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXL, BAP1, BARD1, BCL2, BCL2L1, BCL2L2, BCL6, BCOR, BCORL1, BCR, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTG1, BTG2, BTK, C11orf30, CALR, CARD11, CASP8, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CD22, CD274, CD70, CD74, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CHEK1, CHEK2, CIC, CREBBP, CRKL, CSF1R, CSF3R, CTCF, CTNNA1, CTNNB1, CUL3, CUL4A, CXCR4, CYP17A1, DAXX, DDR1, DDR2, DIS3, DNMT3A, DOT1L, EED, EGFR, EP300, EPHA3, EPHB1, EPHB4, ERBB2, ERBB3, ERBB4, ERCC4, ERG, ERRFI1, ESR1, ETV4, ETV5, ETV6, EWSR1, EZH2, EZR, FAM46C, FANCA, FANCC, FANCG, FANCL, FAS, FBXW7, FGF10, FGF12, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLT1, FLT3, FOXL2, FUBP1, GABRA6, GATA3, GATA4, GATA6, GID4, GNA11, GNA13, GNAQ, GNAS, GRM3, GSK3B, H3F3A, HDAC1, HGF, HNF1A, HRAS, HSD3B1, ID3, IDH1, IDH2, IGF1R, IKBKE, IKZF1, INPP4B, IRF2, IRF4, IRS2, JAK1, JAK2, JAK3, JUN, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KEL, KIT, KLHL6, KMT2A, KMT2D, KRAS, LTK, LYN, MAF, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K13, MAPK1, MCL1, MDM2, MDM4, MED12, MEF2B, MEN1, MERTK, MET, MITF, MKNK1, MLH1, MPL, MRE11A, MSH2, MSH3, MSH6, MST1R, MTAP, MTOR, MUTYH, MYB, MYC, MYCL, MYCN, MYD88, NBN, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NT5C2, NTRK1, NTRK2, NTRK3, NUTM1, P2RY8, PALB2, PARK2, PARP1, PARP2, PARP3, PAX5, PBRM1, PDCD1, PDCD1LG2, PDGFRA, PDGFRB, PDK1, PIK3C2B, PIK3C2G, PIK3CA, PIK3CB, PIK3R1, PIM1, PMS2, POLD1, POLE, PPARG, PPP2R1A, PPP2R2A, PRDM1, PRKAR1A, PRKCI, PTCH1, PTEN, PTPN11, PTPRO, QKI, RAC1, RAD21, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1, RARA, RB1, RBM10, REL, RET, RICTOR, RNF43, ROS1, RPTOR, RSPO2, SDC4, SDHA, SDHB, SDHC, SDHD, SETD2, SF3B1, SGK1, SLC34A2, SMAD2, SMAD4, SMARCA4, SMARCB1, SMO, SNCAIP, SOCS1, SOX2, SOX9, SPEN, SPOP, SRC, STAG2, STAT3, STK11, SUFU, SYK, TBX3, TEK, TERC, TERT, TET2, TGFBR2, TIPARP, TMPRSS2, TNFAIP3, TNFRSF14, TP53, TSC1, TSC2, TYRO3, U2AF1, VEGFA, VHL, WHSC1, WHSC1L1, WT1, XPO1, XRCC2, ZNF217, ZNF703)	Tumor samples fixed (FFPE), DNA extracted from tumor cells	DNA extraction (digestion and extraction), library construction and hybrid capture (enrichment and PCR), sequencing-by-synthesis (Illumina HiSeq)

Analyte (measurement parameter)	Test material (matrix)	Test technique
Somatic gene aberrations in ABI1, ABL1, ABL2, ACSL6, ACTB, AFF1, AFF4, AKT1, AKT2, AKT3, ALK, AMER1, APC, APH1A, AR, ARAF, ARFRP1, ARHGAP26, ARHGEF12, ARID1A, ARID2, ARNT, ASMTL, ASXL1, ATF1, ATG5, ATIC, ATM, ATR, ATRX, AURKA, AURKB, AXIN1, AXL, B2M, BAP1, BARD1, BCL10, BCL11A, BCL11B, BCL2, BCL2L2, BCL3, BCL6, BCL7A, BCL9, BCOR, BCORL1, BCR, BIRC3, BLM, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BRSK1, BTG1, BTG2, BTK, BTLA, C11orf30, CAD, CALR, CAMTA1, CARD11, CARS, CBFA2T3, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CCT6B, CD22, CD274, CD36, CD58, CD70, CD79A, CD79B, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CDX2, CEBPA, CHD2, CHEK1, CHEK2, CHIC2, CHN1, CIC, CIITA , CKS1B, CLP1, CLTC, CLTCL1, CNTRL, COL1A1, CPS1, CREB3L1, CREB3L2, CREBBP, CRKL, CRLF2, CSF1, CSF1R, CSF3R, CTCF, CTNNA1, CTNNB1, CUX1, CXCR4, DAXX, DDIT3, DDR2, DDX10, DDX3X, DDX6, DEK, DNM2, DNMT3A, DOT1L, DTX1, DUSP2, DUSP22, DUSP9, EBF1, ECT2L, EED, EGFR, EIF4A2, ELF4, ELL, ELN, ELP2, EML4, EP300, EPHA3, EPHA5, EPHA7, EPHB1, EPOR, EPS15, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETS1, ETV1, ETV4, ETV5, ETV6, EWSR1, EXOSC6, EZH2, FAF1, FAM46C, FANCA, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCL, FAS, FBXO11, FBXO31, FBXW7, FCGR2B, FCRL4, FEV, FGF10, FGF14, FGF19, FGF23, FGF3, FGF4, FGF6, FGFR1, FGFR1OP, FGFR2, FGFR3, FGFR4, FHIT, FLCN, FLI1, FLT1, FLT3, FLT4, FLYWCH1, FNBP1, FOXL2, FOXO1, FOXO3, FOXO4, FOXP1, FRS2, FSTL3, FUS, GADD45B, GAS7, GATA1, GATA2, GATA3, GID4, GLI1, GMPS, GNA11, GNA12, GNA13, GNAQ, GNAS, GPHN, GPR124, GRIN2A, GSK3B, GTSE1, HDAC1, HDAC4, HDAC7, HERPUD1, HEY1, HGF, HIP1, HIST1H1C, HIST1H1D, HIST1H1E, HIST1H2AC, HIST1H2AG, HIST1H2AL, HIST1H2AM, HIST1H2BC, HIST1H2BJ, HIST1H2BK, HIST1H2BO, HIST1H3B, HIST1H4I, HLF, HMGA1, HMGA2, HNF1A, HOXA11, HOXA13, HOXA3, HOXA9, HOXC11, HOXC13, HOXD11, HOXD13, HRAS, HSP90AA1, HSP90AB1, ICK, ID3, IDH1, IDH2, IGF1R, IGH, IGK, IGL, IKBKE, IKZF1, IKZF2, IKZF3, IL21R, IL3, IL7R, INHBA, INPP4B, INPP5D, IRF1, IRF4, IRF8, IRS2, ITK, JAK1, JAK2, JAK3, JARID2, JAZF1, JUN, KAT6A, KDM2B, KDM4C, KDM5A, KDM5C, KDM6A, KDR, KDSR, KEAP1, KIF5B, KIT, KLHL6, KMT2A, KMT2C, KMT2D, KRAS, LASP1, LCP1, LEF1, LMO1, LMO2, LPP, LRP1B, LRRK2, LYL1, MAF, MAFB, MAGED1, MALT1, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K14, MAP3K6, MAP3K7, MAPK1, MCL1, MDM2, MDM4, MDS2, MECOM, MED12, MEF2B, MEF2C, MEN1, MET, MIB1, MITF, MKI67, MKL1, MLF1, MLH1, MLLT1, MLLT10, MLLT3, MLLT4, MLLT6, MN1, MNX1, MPL, MRE11A, MSH2, MSH3, MSH6, MSI2, MSN, MTOR, MUC1, MUTYH, MYB, MYC, MYCL, MYCN, MYD88, MYH11, MYH9, MYO18A, NACA, NBEAP1, NCOA2,	Extracted nucleic acids (DNA and RNA) from neoplastic cells isolated from peripheral blood, bone marrow aspirate and tumor samples fixed (FFPE)	DNA/RNA extraction (digestion and extraction), cDNA and library construction and hybrid capture (enrichment and PCR), sequencing-by-synthesis (Illumina HiSeq)

Analyte (measurement parameter)	Test material (matrix)	Test technique
NCOR2, NCSTN, NDRG1, NF1, NF2, NFE2L2, NFKB2, NFKBIA, NIN, NKX2-1, NOD1, NOTCH1, NOTCH2, NPM1, NR4A3, NRAS, NSD1, NT5C2, NTRK1, NTRK2, NTRK3, NUMA1, NUP214, NUP93, NUP98, NUTM2A, OMD, P2RY8, PAFAH1B2, PAG1, PAK3, PALB2, PASK, PAX3, PAX5, PAX7, PBRM1, PBX1, PC, PCBP1, PCLO, PCM1, PCSK7, PDCD1, PDCD11, PDCD1LG2, PDE4DIP, PDGFB, PDGFRA, PDGFRB, PDK1, PER1, PHF1, PHF6, PICALM, PIK3CA, PIK3CG, PIK3R1, PIK3R2, PIM1, PLAG1, PLCG2, PML, POT1, POU2AF1, PPP1CB, PPP2R1A, PRDM1, PRDM16, PRKAR1A, PRKDC, PRRX1, PRSS8, PSIP1, PTCH1, PTEN, PTK7, PTPN11, PTPN2, PTPN6, PTPRO, RABEP1, RAD21, RAD50, RAD51, RAF1, RALGDS, RAP1GDS1, RARA, RASGEF1A, RB1, RBM15, RELN, RET, RHOA, RHOH, RICTOR, RNF213, RNF43, ROS1, RPL22, RPN1, RPTOR, RUNX1, RUNX1T1, RUNX2, S1PR2, SDHA, SDHB, SDHC, SDHD, SEC31A, SEPT5, SEPT6, SEPT9, SERP2, SET, SETBP1, SETD2, SF3B1, SGK1, SH3GL1, SLC1A2, SMAD2, SMAD4, SMARCA1, SMARCA4, SMARCB1, SMC1A, SMC3, SMO, SNX29, SOCS1, SOCS2, SOCS3, SOX10, SOX2, SPEN, SPOP, SRC, SRSF2, SRSF3, SS18, SSX1, SSX2, SSX4, STAG2, STAT3, STAT4, STAT5A, STAT5B, STAT6, STK11, STL, SUFU, SUZ12, SYK, TAF1, TAF15, TAL1, TAL2, TBL1XR1, TCF3, TCL1A, TEC, TET1, TET2, TFE3, TFG, TFPT, TFRC, TGFBR2, TLL2, TLX1, TLX3, TMEM30A, TMPRSS2, TMSB4XP8, TNFAIP3, TNFRSF11A, TNFRSF14, TNFRSF17, TOP1, TP53, TP63, TPM3, TPM4, TRAF2, TRAF3, TRAF5, TRG, TRIM24, TRIP11, TSC1, TSC2, TSHR, TTL, TUSC3, TYK2, U2AF1, U2AF2, USP6, VHL, WDR90, WHSC1, WHSC1L1, WISP3, WT1, XBP1, XPO1, YPEL5, YY1AP1, ZBTB16, ZMYM2, ZMYM3, ZNF217, ZNF24, ZNF384, ZNF521, ZNF703, ZRSR2		