

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-20456-01-00 according to DIN EN ISO/IEC 17025:2018

Period of validity: 24.04.2019 to 05.04.2023

Date of issue: 24.04.2019

Holder of certificate:

Pathonext GmbH
Deutscher Platz 5b, 04103 Leipzig

Tests in the fields:

Health care (genetic diagnostics)

Testing area:

Genetic diagnostics

Within the given testing field marked with **, the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the following: the modification, development and refinement of testing methods. The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

Testing area: Genetic diagnostics

Type of test: Sequencing**

Analyte (Parameter)	Test specimen (Matrix)	Testing technology
BRCA DNA Repair Panel - TSCA LI: Coding sequence BRCA1 and BRCA2	DNA	Illumina, MiSeq Amplicon, Sequencing-by synthesis Databases: NCBI (reference genome), COSMIC, ClinVar, 1000 Genomes Project, ExAc, dbSNP common, dbSNP, UCSC, ARUP BRCA Mutation Database, LOVD BRCA1, LOVD BRCA2
TruSight Tumor 15: BRAF (E15) , EGFR (E12, E18, E19, E20, E21), ERBB2 (E17, E18, E19, E20, E21, E24, E26), FOXL2 (E01), GNA11 (E05), GNAQ (E05), KIT (E08, E09, E10, E11, E13, E14, E17, E18), KRAS (E02, E03, E04), MET (E16, E18, E20), NRAS (E02, E03, E04), PDGFRA (E12, E14, E18), PIK3CA (E09, E20), RET (E16), TP53 (entire coding region)	DNA	Illumina, MiSeq Amplicon, Sequencing-by synthesis Databases: NCBI (reference genome), COSMIC, ClinVar, 1000 Genomes Project, ExAc, dbSNP common, dbSNP, UCSC, IARC TP53 Database, LOVD TP53

Abbreviations used:

DIN Deutsches Institut für Normung e.V.