

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-13206-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 16.10.2023

Date of issue: 20.03.2025

Holder of accreditation certificate:

CeGaT GmbH

Paul-Ehrlich-Straße 23, 72076 Tübingen

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing 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/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Tests in the fields:

Health Care (nucleic acid analysis)

Health Care (medical laboratory examination in the context of clinical studies)

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 <https://www.dakks.de>.

Abbreviations used: see last page

Within the given testing field marked with **, the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, 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.

Field: Health Care (Nucleic acid analysis)

Testing area: Nucleic acid analysis

Type of test:

Nucleic acid amplification (incl. purification and enrichment)**

Analyte (measured value)	Test material (matrix)	Testing technique
SNPs, Copy number variations (CNVs)	DNA, DNA from tissue, FFPE, blood, plasma, serum, cell culture	ddPCR

Type of test:

Next generation sequencing incl. preparation and data analysis**

Analyte (measured value)	Test material (matrix)	Testing technique
DNA-/RNA-Sequence	DNA or RNA from blood, plasma, serum, tissue, FFPE, bacteria, stool samples NGS-Library, PCR-products, plasmid-DNA	Sequencing by synthesis incl. sample preparation, library preparation, quality controls and Bio-IT-analysis

Field: Health Care (medical laboratory examination in the context of clinical studies)

Testing area: Human genetics (molecular human genetics)

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

Analyte (measured value)	Test material (matrix)	Testing technique
<i>Whole Exome Sequencing</i> <i>Whole Genome Sequencing</i>	DNA from blood, plasma, serum, tissue, FFPE, NGS-Library, PCR-products	Sequencing by synthesis incl. sample preparation, library preparation, quality controls and Bio-IT-analysis
<i>Transcriptome Sequencing</i>	RNA from blood, plasma, serum, tissue, FFPE, NGS-Library, PCR-products	Sequencing by synthesis incl. sample preparation, library preparation, quality controls and Bio-IT-analysis

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Analyte (measured value)	Test material (matrix)	Testing technique
SNPs, Copy number variations (CNVs) <i>BAP1, BRAF, CDK4, EGFR, FGFR3, GNA11, GNAQ, JAK2, KIT, KRAS, MAP2K1, MLH1, MYCN, NF1, NRAS, PIK3CA, STAT1, TP53, SLC34A2-Ros1</i>	DNA, DNA from tissue, FFPE, blood, plasma, serum, cell culture	ddPCR

Testing area: Human genetics (cytogenetics)

Type of test: Chromosome analysis

Analyte (measured value)	Test material (matrix)	Testing technique
Genome imbalances (duplications / deletions)	EDTA-Blood, DNA from blood, cell culture, genomic DNA	Molecular karyotyping by array analysis (Array-CGH)

Abbreviations used:

CNVs	Copy Number Variations
DIN	Deutsches Institut für Normung e.V. – German institute for standardization
DNA	Desoxyribonucleic acid
ddPCR	Droplet digital PCR
EN	Europäische Norm – European Standard
FFPE	Formalin-Fixed Paraffin-Embedded
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation
NGS	Next Generation Sequencing
PBMC	Peripheral blood mononuclear cells
PCR	Polymerase Chain Reaction
RNA	Ribonucleic acid
SNPs	Single Nucleotide Polymorphisms
SOP	Standard Operating Procedure

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