

Deutsche Akkreditierungsstelle

Annex to the accreditation certificate D-PL-13372-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: 04.03.2026

Date of issue: 04.03.2026

This annex is part of the accreditation certificate D-PL-13372-01-00.

Holder of the accreditation certificate:

**Eurofins Genomics Europe Food/Environment/White Biotech Products & Services
GmbH
Anzinger Str. 7a, 85560 Ebersberg**

with the location

**Eurofins Genomics Europe Food/Environment/White Biotech Products & Services
GmbH
Anzinger Str. 7, 85560 Ebersberg**

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.

*This annex to the certificate was issued by Deutsche Akkreditierungsstelle GmbH (DAkkS) and is digitally sealed.
This annex to the certificate 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 valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).*

Annex to the accreditation certificate D-PL-13372-01-02

Tests in the fields:

Pharmaceutical products, medical laboratory tests in clinical trials (Human genetics), nucleic acid analysis

Flexible scope of accreditation:

Within the test areas indicated, the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS

[Flex C] to modify, develop or further develop test methods.

The test methods listed are examples. The testing laboratory has an up-to-date list of all test methods within the flexible scope of accreditation. The list is publicly available on the website of the testing laboratory.

Pharmaceutical products
Biological tests [Flex C]

Standard/date of issue In-house method/version	Analyte – Title of standard Specification for sample pretreatment / testing	Test item
SOP APG_Mycoplasma_test_ 9.0 08.05.2025	Detection of mycoplasma DNA in supernatants Sequence-specific detection of amplification products, quantitative using real-time PCR	Eluates from pharmaceutical intermediate products or cell lines

Medical laboratory tests in clinical trials (Human genetics)
Molecular biological analysis (amplification methods) [Flex C]

Analyte (measurand)	Test material (matrix)	Test technique	Instruction/version
Genetic variants in human genes	Human DNA, genomic, isolated from blood or other suitable matrices	Long-range PCR followed by fragment length analysis (FLA)	SOP_APG_Genotypisierung_Pharma_3.0
Genotyping of cell lines to determine authenticity	Cell pellets or genomic DNA	PCR followed by fragment length analysis (FLA)	SOP_APG_Zelllinienauthentizität_3.0

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Nucleic acid analysis
Nucleic acid extraction including quality control [Flex C]

Analyte (measurand)	Test material (matrix)	Test technique	Instruction/version
Determination of the amount of DNA	Biological sample material (human stool samples)	Isolation for determination of the DNA amount with - M&N Nucleospin Soil Kit - M&N NucleoMAG DNA Microbiome Kit with subsequent QC (OD measurement)	SOP_APG_DNA-Extraction_6.0

High-throughput sequencing, including sample preparation and data analysis [Flex C]

Analyte (measurand)	Test material (matrix)	Test technique	Instruction/version
DNA sequence	DNA from - Blood - Tissue - Stool samples - Bacteria	Sequencing by Oxford Nanopore platform (GridION Mk 1) incl. - Sample Preparation - Library preparation - Analysis of sequencing data using BiolT analysis	SOP_NGS-KN_DNA-Isolierung_QIAamp_DNA_Mini_Kit_1.0 SOP_NGS-KN_RNA-extraction_1.0 SOP_NGS-KN_Autom_RNA_EntryQC_1.0 SOP_NGS-KN_AutomEntryQC_5.0 SOP_NGS-KN_ONT_Operations_GridION_P2Solo_1.0 SOP_NGS-KN_ONT_library_preparation_1.0
DNA/RNA sequence	DNA or RNA from - Blood - Plasma - Serum - Tissue - FFPE - Stool samples - Bacteria - Viruses	Sequencing by Synthesis (Illumina platform) incl. - Sample preparation - Library preparation - Analysis of sequencing data using BiolT analysis (BiolT pipeline) and public databases	SOP_NGS-KN_DNA-Isolierung_QIAamp_DNA_Mini_Kit_1.0 SOP_NGS-KN_RNA-extraction_1.0 SOP_NGS-KN_Autom_RNA_EntryQC_1.0 SOP_NGS-KN_AutomEntryQC_5.0 SOP_NGS-KN_Std_DNA_Lib_Prep_6.0 SOP_NGS-KN_Autom_RNA_Lib_Prep_GxP_1.0 SOP_NGS-KN_OperationMiSeq_3.0 SOP_NGS-KN_OperationNovaSeqX_Plus_1.0 SOP_NGS-KN_Mini_Amplikon_2.0

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Abbreviations used:

DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
DNA	deoxyribonucleic acid
EN	European standard
FFPE	Formalin-fixed, Paraffin-embedded
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation
PCR	Polymerase chain reaction
RNA	Ribonucleic Acid
SOP...	In-house method of Eurofins Genomics Europe Food/Environment/White Biotech Products & Services GmbH

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