Deutsche Akkreditierungsstelle

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

Valid from: **22.08.2025**

Date of issue: 03.11.2025

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 ofDIN 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:

Pharmaceutical products, medical laboratory tests in clinical trials, 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_ 7.0 2023-11	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 (human molecular genetics)

Molecular biological analysis (amplification methods) [Flex C]

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

Nucleic acid analysis

Nucleic acid extraction [Flex C]

Analyte (measurand)	Test material (matrix)	Test technique
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 - Qiagen Fast DNA Stool Kit with subsequent QC (OD measurement; fluorescence measurement)

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
DNA	deoxyribonucleic acid
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation
RT-qPCR	Real-time quantitative polymerase chain reaction PCR
SOP…	In-house method of Eurofins Genomics Europe Food/Environment/White Biotech Products & Services GmbH