

Accreditation



The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the medical laboratory

MLM Medical Labs GmbH
Dohrweg 63, 41066 Mönchengladbach

meets the requirements according to DIN EN ISO 15189:2024 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the medical laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories and they conform to the principles of DIN EN ISO 9001.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notices of 01.07.2025 with accreditation number D-ML-13178-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 9 pages.

Registration number of the accreditation certificate: **D-ML-13178-01-00**

Berlin, 01.07.2025

Dr.-medic Simona Curelea
Head of Technical Unit

Translation issued:
21.07.2025

in Vertretung von Dr. Curelea
Dr.-medic Simona Curelea
Head of Technical Unit

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 can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

Office Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Office Braunschweig
Bundesallee 100
38116 Braunschweig

The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:

EA: www.european-accreditation.org

ILAC: www.ilac.org

IAF: www.iaf.nu

Deutsche Akkreditierungsstelle

Annex to the accreditation certificate D-ML-13178-01-00 according to DIN EN ISO 15189:2024

Valid from: 01.07.2025

Date of issue: 01.07.2025

Holder of the accreditation certificate:

MLM Medical Labs GmbH
Dohrweg 63, 41066 Mönchengladbach

with the location

MLM Medical Labs GmbH
Dohrweg 63, 41066 Mönchengladbach

The medical laboratory meets the requirements pursuant to DIN EN ISO 15189:2024 necessary to carry out the conformity assessment activities set out in this annex. The medical laboratory meets, where applicable, additional legal and normative requirements, including those set out in relevant sectoral schemes, provided that these are expressly confirmed below.

The management system requirements of DIN EN ISO 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.

This certificate annex is valid only together with the certificate issued in writing and reflects the status as indicated by the date of issue. The current status of the valid and monitored accreditation can be found in the database of accredited bodies maintained by Deutsche Akkreditierungsstelle (www.dakks.de)

Analysis in area:

Medical laboratory diagnostics

Test areas:

Clinical chemistry

Virology

Flexible scope of accreditation:

Within the marked test areas, the medical laboratory is permitted to apply the listed standardised or equivalent test methods with different versions of the standards without obtaining prior notification and consent from DAkkS [Flex A]. In the medical laboratory sector, equivalent test methods in this category also include test methods validated by the laboratory and confirmed by an accreditation decision. This applies exclusively to new versions (revisions) of confirmed test methods without any changes to the analyte, matrix or test technique.

[Flex B] Freely select standard test methods or equivalent test methods.

The test methods listed are given by way of an example. The medical laboratory has an up-to-date list of all test methods within the flexible scope of accreditation. The list is publicly available on the medical laboratory's website.

Test area: Clinical chemistry

Type of test:

Agglutination tests ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
CRP	Serum, EDTA plasma, Li-heparin plasma	Latex agglutination test
Cystatin C	Serum, EDTA plasma, Li-heparin plasma	Latex agglutination test

Type of test:

Chromatography (high performance liquid chromatography (HPLC)) ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Adrenaline	EDTA plasma	HPLC - ECD
Adrenaline	Urine	HPLC - ECD
HbA1c	EDTA blood	HPLC - ion exchange
Noradrenaline	EDTA plasma	HPLC - ECD
Noradrenaline	Urine	HPLC - ECD

Type of test:

Flow cytometry ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Complete blood count	EDTA blood	Cell count/ differentiation
Blood count	EDTA blood	Cell count/ differentiation
Reticulocytes	EDTA blood	Cell count/ differentiation

Type of test:

Electrochemical tests ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Chloride	Serum, heparin plasma, urine	Potentiometry (ISE)
Potassium	Serum, heparin plasma, urine	Potentiometry (ISE)
Sodium	Serum, heparin plasma, urine	Potentiometry (ISE)

Type of test:

Coagulometry ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
aPTT	Citrate plasma	Coagulometry
D-Dimer	Citrate plasma	Coagulometry
Fibrinogen	Citrate plasma	Coagulometry
Prothrombin time (PT/Quick/INR)	Citrate plasma	Coagulometry
Thrombin time	Citrate plasma	Coagulometry

Type of test:

Ligand assays ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Amphetamines	Urine	KIMS
Barbiturate	Urine	KIMS
Benzodiazepine	Urine	KIMS
Cannabinoids	Urine	KIMS
Cocaine + metabolites	Urine	KIMS
Methadone + metabolites	Urine	KIMS
Opiates	Urine	KIMS
Phencyclidine + metabolites	Urine	KIMS
Cortisol	Serum, EDTA plasma, Li-heparin plasma	ECLIA
C-peptide	Serum, EDTA plasma, Li-heparin plasma, urine	ECLIA
Estradiol	Serum, EDTA plasma, Li-heparin plasma	ECLIA
Ferritin	Serum, EDTA plasma, heparin plasma	ECLIA
FSH	Serum, EDTA plasma, heparin plasma	ECLIA
FT3	Serum, EDTA plasma, Li-heparin plasma	ECLIA
FT4	Serum, EDTA plasma, Li-heparin plasma	ECLIA

Annex to the accreditation certificate D-ML-13178-01-00

Analyte (measurand)	Test material (matrix)	Test technique
Glucagon	EDTA plasma + aprotinin P800 plasma	RIA
hCG-β	Serum EDTA plasma Heparin plasma Urine	ECLIA
IL-6	Serum EDTA plasma Li-heparin plasma	ECLIA
Insulin	Serum EDTA plasma Li-heparin plasma	ECLIA
LH	Serum EDTA plasma Heparin plasma NaF plasma	ECLIA
NT-proBNP	Serum EDTA plasma Heparin plasma	ECLIA
Progesterone	Serum EDTA plasma Heparin plasma NaF plasma	ECLIA
Prolactin	Serum EDTA plasma Li-heparin plasma	ECLIA
Renin activity	EDTA plasma	RIA
T3	Serum EDTA plasma Heparin plasma NaF plasma Citrate plasma	ECLIA
T4	Serum EDTA plasma Heparin plasma	ECLIA

Analyte (measurand)	Test material (matrix)	Test technique
Testosterone	Serum EDTA plasma Li-heparin plasma	ECLIA
Tricyclic antidepressants	Urine	EIA
Troponin T	Serum EDTA plasma Heparin plasma	ECLIA
TSH	Serum EDTA plasma Heparin plasma NaF plasma Citrate plasma	ECLIA

Type of test:

Microscopy ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Urine sediment	Urine	Bright-field microscopy

Type of test:

Osmometry ^[Flex A]

Analyte (measurand)	Test material (matrix)	Test technique
Osmolality	Serum, urine	Cryoscopy

Type of test:

Spectrometry (UV/VIS photometry) ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
ALAT (ALT, GPT)	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Albumin	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Alkaline phosphatase	Serum Li-heparin plasma	UV/VIS photometry
Alcohol / ethanol	Serum EDTA plasma Li-heparin plasma Urine	UV/VIS photometry
Amylase α	Serum Li-heparin plasma Urine	UV/VIS photometry

Annex to the accreditation certificate D-ML-13178-01-00

Analyte (measurand)	Test material (matrix)	Test technique
ASAT (AST, GOT)	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Bicarbonate	Serum Li-heparin plasma	UV/VIS photometry
Bilirubin total	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Bilirubin direct	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Calcium	Serum Li-heparin plasma Urine (acidified)	UV/VIS photometry
Cholesterol	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Cholinesterase	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
CK	Serum Li-heparin plasma	UV/VIS photometry
CK-MB	Serum Li-heparin plasma	UV/VIS photometry
Creatinine	Serum EDTA plasma Li-heparin plasma Urine	UV/VIS photometry
Iron	Serum Li-heparin plasma	UV/VIS photometry
GGT	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
GLDH	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Glucose	Serum NaF plasma Urine	UV/VIS photometry
Uric acid	Serum EDTA plasma Li-heparin plasma Urine	UV/VIS photometry
Urea	Serum EDTA plasma Li-heparin plasma Urine	UV/VIS photometry

Valid from: 01.07.2025

Date of issue: 01.07.2025

Analyte (measurand)	Test material (matrix)	Test technique
HDL cholesterol	Serum Li-heparin plasma	UV/VIS photometry
Hydroxybutyrate dehydrogenase (HBDH)	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Lactate	NaF plasma Na-heparin plasma Cerebrospinal fluid	UV/VIS photometry
LDH	Serum Li-heparin plasma	UV/VIS photometry
LDL cholesterol	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Lipase	Serum Li-heparin plasma	UV/VIS photometry
Magnesium	Serum Li-heparin plasma Urine (acidified)	UV/VIS photometry
Pancreatic amylase	Serum Li-heparin plasma Urine	UV/VIS photometry
Phosphate	Serum EDTA plasma Li-heparin plasma Urine	UV/VIS photometry
Total protein	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry
Triglycerides	Serum EDTA plasma Li-heparin plasma	UV/VIS photometry

Type of test:

Spectrometry (reflectometry /carrier test methods) ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Bilirubin	Urine	Reflectance photometry
Glucose	Urine	Reflectance photometry
Haemoglobin	Urine	Reflectance photometry
Ketone	Urine	Reflectance photometry
Leukocytes	Urine	Reflectance photometry
Nitrite	Urine	Reflectance photometry
pH value	Urine	Reflectance photometry
Protein	Urine	Reflectance photometry
Specific gravity	Urine	Reflectance photometry
Urobilinogen	Urine	Reflectance photometry

Valid from: 01.07.2025

Date of issue: 01.07.2025

Type of test:

Spectrometry (turbidimetry) ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Albumin	Urine	Turbidimetry
Total protein	Urine	Turbidimetry
Transferrin	Serum, Li-heparin plasma	Turbidimetry

Test area: Virology

Type of test:

Ligand assays ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
Hepatitis Bs antigen	Serum EDTA plasma Heparin plasma Citrate plasma	ECLIA
Hepatitis C antibodies	Serum EDTA plasma Heparin plasma Citrate plasma	ECLIA
HIV 1/2 antibodies	Serum EDTA plasma Li-heparin plasma	ECLIA

Type of test:

Molecular biological analysis ^[Flex B]

Analyte (measurand)	Test material (matrix)	Test technique
SARS-CoV-2	Nasal, throat and nasopharyngeal swab	RT PCR