

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Signatory to the Multilateral Agreements of
EA, ILAC and IAF for Mutual Recognition

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the medical laboratory

MLM Medical Labs GmbH
Dohrweg 63, 41066 Mönchengladbach

is competent under the terms of DIN EN ISO 15189:2014 to carry out examinations in the following field:

Medical Laboratory Diagnostics

Medical laboratory fields:

Clinical chemistry

Virology

The accreditation certificate shall only apply in connection with the notice of accreditation of 12.08.2021 with the accreditation number D-ML-13178-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 8 pages.

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

Frankfurt am Main, 12.08.2021

Dipl.-Biol. Uwe Zimmermann
Head of Division

Translation issued:
12.08.2021



Head of Division

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<https://www.dakks.de/en/content/accredited-bodies-dakks>

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

See notes overleaf.

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The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkKS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkKS.

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). 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 Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

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 GmbH

Annex to the Accreditation Certificate D-ML-13178-01-00 according to DIN EN ISO 15189:2014

Valid from: 12.08.2021

Date of issue: 12.08.2021

Holder of certificate:

MLM Medical Labs GmbH

Dohrweg 63, 41066 Mönchengladbach

Examinations in the field:

Medical Laboratory Diagnostics

Medical laboratory fields:

Clinical chemistry

Virology

Within the given type of examination marked with *), the medical laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the free choice of standards or equivalent examination procedures.

The listed examination procedures are exemplary. The medical laboratory maintains a current list of all examination procedures within the flexible scope of accreditation.

The requirements for the management system in DIN EN ISO 15189 are written in a language relevant to medical laboratories and are generally in accordance with the principles of DIN EN ISO 9001.

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

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.

<https://www.dakks.de/en/content/accredited-bodies-dakks>

Medical laboratory field: Clinical chemistry

Type of test:

Agglutination tests*

Analyte (Parameter)	Specimen	Method
Amphetamine	Urine	KIMS
Barbiturate	Urine	KIMS
Benzodiazepine	Urine	KIMS
Cannabinoids	Urine	KIMS
Cocaine + metabolits	Urine	KIMS
CRP	Serum EDTA plasma Li-Heparin plasma	latex agglutination test
Cystatin C	Serum EDTA plasma Li-Heparin plasma	latex agglutination test
Methadone + metabolits	Urine	KIMS
Opiate	Urine	KIMS
Phencyclidine + metabolits	Urine	KIMS

Type of test:

Chromatography (high performance liquid chromatography (HPLC))*

Analyte (Parameter)	Specimen	Method
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*

Analyte (Parameter)	Specimen	Method
Complete blood count	EDTA blood	cell-number determination / differentiation
Blood count	EDTA blood	cell-number determination / differentiation
Reticulocytes	EDTA blood	cell-number determination / differentiation

Type of test:

Electrochemical tests*

Analyte (Parameter)	Specimen	Method
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*

Analyte (Parameter)	Specimen	Method
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*

Analyte (Parameter)	Specimen	Method
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

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Analyte (Parameter)	Specimen	Method
FT3	Serum EDTA plasma Li-Heparin plasma	ECLIA
FT4	Serum EDTA plasma Li-Heparin plasma	ECLIA
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
Testosterone	Serum EDTA plasma Li-Heparin plasma	ECLIA
Tricyclic antidepressants	Urine	EIA

Analyte (Parameter)	Specimen	Method
Troponin T	Serum EDTA plasma Heparin plasma	ECLIA
TSH	Serum EDTA plasma Heparin plasma NaF plasma Citrate plasma	ECLIA

Type of test:

Microscopy*

Analyte (Parameter)	Specimen	Method
Urine sediment	Urine	Bright-field microscopy

Type of test:

Osmometry

Analyte (Parameter)	Specimen	Method
Osmolality	Serum Urine	Cryoscopy

Type of test:

Spectrometry (UV/VIS photometry)*

Analyte (Parameter)	Specimen	Method
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
ASAT (AST, GOT)	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry

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Analyte (Parameter)	Specimen	Method
Bicarbonate	Serum, Li-Heparin plasma	UV/VIS photometry
Bilirubin total	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry
Bilirubin directly	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
HDL cholesterol	Serum Li-Heparin plasma	UV/VIS photometry

Analyte (Parameter)	Specimen	Method
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)*

Analyte (Parameter)	Specimen	Method
Bilirubin	Urine	reflectance photometry
Glucose	Urine	reflectance photometry
Hemoglobin	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 weight	Urine	reflectance photometry
Urobilinogen	Urine	reflectance photometry

Type of test:

Spectrometry (turbidimetry)*

Analyte (Parameter)	Specimen	Method
Albumin	Urine	turbidimetry
Protein total	Urine	turbidimetry
Transferrin	Serum Li-Heparin plasma	turbidimetry

Type of test:

Spectrometry (nephelometry)*

Analyte (Parameter)	Specimen	Method
Cystatin C	Serum	nephelometry

Medical laboratory field: Virology

Type of test:

Ligand assays*

Analyte (Parameter)	Specimen	Method
Hepatitis Bs antigen	Serum EDTA plasma Li-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 tests (amplification procedures)*

Analyte (Parameter)	Specimen	Method
SARS-CoV-2	Nasal, pharyngeal and nasopharyngeal smear	Real-time qPCR