

MLM Medical Labs GmbH is accredited according to DIN EN ISO 15189:2014 by the German Accreditation Body DAkkS.

Within the flexible scope of accreditation, MLM Medical Labs is permitted to modify and further develop or develop new test procedures without information or prior approval from DAkkS.

The currently validated test methods in the flexible test areas marked with \* are listed below

**Medical laboratory field: Clinical chemistry**

**Type of examination :**

**Agglutination tests\***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
CRP	Serum EDTA plasma Li-Heparin plasma	Latex agglutination test	SOP-MG-LAB.M.0017.4	Roche Cobas® 6000	x	
Cystatin C	Serum EDTA plasma Li-Heparin plasma	Latex agglutination test	SOP-MG-LAB.M.0064.8	Roche Cobas® 6000	x	

**Type of examination :**

**Chromatography (High performance liquid chromatography (HPLC)) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
HbA1c	EDTA blood	HPLC - ion exchange	SOP-MG-LAB.M.0083.8	TOSOH G8	x	

**Type of examination:**

**Flow cytometry \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Complete blood count	EDTA blood	Cell-number determination / differentiation	SOP-MG-LAB.M.0125.4	Sysmex XN-1000	x	
Blood count	EDTA blood	Cell-number determination / differentiation	SOP-MG-LAB.M.0125.4	Sysmex XN-1000	x	
Reticulocytes	EDTA blood	Cell-number determination / differentiation	SOP-MG-LAB.M.0125.4	Sysmex XN-1000	x	
Lymphocytes (T-, B-, NK-cells)	EDTA blood	Immunphenotyping of immune cell populations	SOP-MG-FLC.M.0005.1	BD FACSLyric	x	

**Type of examination:**

**Electrochemical tests \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Chloride	Serum Li-Heparin plasma Urine	Potentiometry (ISE)	SOP-MG-LAB.M.0034.3	Roche Cobas® 6000	x	
Potassium	Serum Li-Heparin plasma Urine	Potentiometry (ISE)	SOP-MG-LAB.M.0024.5	Roche Cobas® 6000	x	
Sodium	Serum Li-Heparin plasma Urine	Potentiometry (ISE)	SOP-MG-LAB.M.0033.5	Roche Cobas® 6000	x	

**Type of examination:**

**Coagulometry \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
aPTT	Citrate plasma	Coagulometry	SOP-MG-LAB.M.0076.6	Stago STA Compact Max® 3	x	
D-Dimer	Citrate plasma	Coagulometry	SOP-MG-LAB.M.0078.7	Stago STA Compact Max® 3	x	
Fibrinogen	Citrate plasma	Coagulometry	SOP-MG-LAB.M.0075.6	Stago STA Compact Max® 3	x	
Prothrombin time (PT/Quick/INR)	Citrate plasma	Coagulometry	SOP-MG-LAB.M.0152.5	Stago STA Compact Max® 3	x	
Thrombin time	Citrate plasma	Coagulometry	SOP-MG-LAB.M.0086.6	Stago STA Compact Max® 3	x	

**Type of examination:**

**Ligand assays \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Amphetamine	Urine	KIMS	SOP-MG-LAB.M.0096.6	Roche Cobas® 6000	x	
β-Amyloid (1-42)	EDTA plasma	CLEIA	SOP-MG-MDL.M.0041.1	Lumipulse G1200		x
Barbiturate	Urine	KIMS	SOP-MG-LAB.M.0097.6	Roche Cobas® 6000	x	
Benzodiazepine	Urine	KIMS	SOP-MG-LAB.M.0098.6	Roche Cobas® 6000	x	
Cannabinoids	Urine	KIMS	SOP-MG-LAB.M.0099.4	Roche Cobas® 6000	x	
Cocain + metabolits	Urine	KIMS	SOP-MG-LAB.M.0100.5	Roche Cobas® 6000	x	
Cortisol	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0003.4	Roche Cobas® 6000	x	
C-peptide	Serum EDTA plasma Urine	ECLIA	SOP-MG-LAB.M.0039.9	Roche Cobas® 6000	x	
Estradiol	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0089.5	Roche Cobas® 6000	x	
Ferritin	Serum EDTA plasma Heparin plasma	ECLIA	SOP-MG-LAB.M.0025.5	Roche Cobas® 6000	x	
FSH	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0012.3	Roche Cobas® 6000	x	

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
FT3	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0069.5	Roche Cobas® 6000	x	
FT4	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0071.4	Roche Cobas® 6000	x	
Glucagon	EDTA plasma + aprotinin P800 plasma	RIA	SOP-MG-RIA.M.0001.10	Perkin Elmer Gamma Counter Wizard 2470	x	
hCG-β	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0067.6	Roche Cobas® 6000	x	
IL-6	Serum EDTA plasma	ECLIA	SOP-MG-LAB.M.0090.4	Roche Cobas® 6000	x	
Insulin	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0002.8	Roche Cobas® 6000	x	
KL-6	Serum EDTA plasma	CLEIA	SOP-MG-MDL.M.0032.4	Lumipulse G1200		x
LH	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0011.4	Roche Cobas® 6000	x	
Methadone + metabolits	Urine	KIMS	SOP-MG-LAB.M.0101.7	Roche Cobas® 6000	x	
NT-pro BNP	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0008.5	Roche Cobas® 6000	x	
Opiate	Urine	KIMS	SOP-MG-LAB.M.0102.5	Roche Cobas® 6000	x	
Phencyclidine + metabolits	Urine	KIMS	SOP-MG-LAB.M.0110.5	Roche Cobas® 6000	x	
Progesterone	Serum EDTA-plasma Li-Heparin-plasma	ECLIA	SOP-MG-LAB.M.0010.3	Roche Cobas® 6000	x	
Prolactin	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0009.4	Roche Cobas® 6000	x	
pTau (217)	EDTA plasma	CLEIA	SOP-MG-MDL.M.0035.3	Lumipulse G1200		x
pTau (217) / β-Amyloid (1-42) Ratio	n.a.	Calculated parameter (see β-Amyloid (1-42) and pTau (217))	SOP-MG-MDL.M.0035.3	n.a.		x
Renin activity	EDTA plasma	RIA	SOP-MG-RIA.M.0006.5	Perkin Elmer Gamma Counter Wizard 2470	x	
T3	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0068.3	Roche Cobas® 6000	x	

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
T4	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0070.4	Roche Cobas® 6000	x	
Testosterone	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0095.3	Roche Cobas® 6000	x	
Tricyclic antidepressants	Urine	EIA	SOP-MG-LAB.M.0048.6	Roche Cobas® 6000	x	
Troponin T	Serum EDTA plasma Heparin plasma	ECLIA	SOP-MG-LAB.M.0079.7	Roche Cobas® 6000	x	
TSH	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0072.4	Roche Cobas® 6000	x	
25-OH-Vitamin D3	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0130.3	Roche Cobas® 6000	x	

**Type of examination:**

**Microscopy \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Urine sediment	Urine	Bright-field microscopy	SOP-MG-LAB.M.0082.5	Manual	x	

**Type of examination:**

**Spectrometry - UV/VIS spectrometry \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
ALAT (ALT, GPT)	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0019.5	Roche Cobas® 6000	x	
Albumin	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0029.4	Roche Cobas® 6000	x	
Alkaline phosphatase	Serum Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0028.4	Roche Cobas® 6000	x	
Alcohol/ Ethanol	Serum EDTA-Plasma Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0103.3	Roche Cobas® 6000	x	
Amylase α	Serum Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0058.5	Roche Cobas® 6000	x	
ASAT (AST, GOT)	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0018.6	Roche Cobas® 6000	x	

**List of Test Procedures  
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ML-13178-01**

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Bicarbonate	Serum Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0036.5	Roche Cobas® 6000	x	
Bilirubin total	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0021.4	Roche Cobas® 6000	x	
Bilirubin direct	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0060.6	Roche Cobas® 6000	x	
Calcium	Serum Li-Heparin plasma Urine (acidified)	UV/VIS photometry	SOP-MG-LAB.M.0027.5	Roche Cobas® 6000	x	
Cholesterol	Serum Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0052.5	Roche Cobas® 6000	x	
Cholinesterase	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0059.4	Roche Cobas® 6000	x	
CK	Serum Li-Heparin plasma EDTA plasma	UV/VIS photometry	SOP-MG-LAB.M.0053.5	Roche Cobas® 6000	x	
CK-MB	Serum Li-Heparin plasma EDTA plasma	UV/VIS photometry	SOP-MG-LAB.M.0054.7	Roche Cobas® 6000	x	
Creatinine	Serum EDTA plasma Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0035.6	Roche Cobas® 6000	x	
Iron	Serum Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0074.3	Roche Cobas® 6000	x	
GGT	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0020.4	Roche Cobas® 6000	x	
GLDH	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0061.5	Roche Cobas® 6000	x	
Glucose	Sodium-Fluorid EDTA plasma Citrate-Fluorid EDTA plasma Urine Cerebrospinal fluid	UV/VIS photometry	SOP-MG-LAB.M.0022.9	Roche Cobas® 6000	x	
HDL-cholesterol	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0055.5	Roche Cobas® 6000	x	
Hydroxybutyrate dehydrogenase (HBDH)	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0063.3	Roche Cobas® 6000	x	

**List of Test Procedures  
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Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Lactate	NaF-Plasma Na-Heparin plasma Cerebrospinal fluid	UV/VIS photometry	SOP-MG-LAB.M.0062.4	Roche Cobas® 6000	x	
LDH	Serum Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0030.7	Roche Cobas® 6000	x	
LDL cholesterol	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0056.5	Roche Cobas® 6000	x	
Lipase	Serum Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0057.7	Roche Cobas® 6000	x	
Magnesium	Serum Li-Heparin plasma Urine (acidified)	UV/VIS photometry	SOP-MG-LAB.M.0038.6	Roche Cobas® 6000	x	
Pancreatic amylase	Serum Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0113.3	Roche Cobas® 6000	x	
Phosphate	Serum EDTA plasma Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0026.6	Roche Cobas® 6000	x	
Total protein	Serum EDTA-Plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0031.5	Roche Cobas® 6000	x	
Triglycerides	Serum EDTA plasma Li-Heparin plasma	UV/VIS photometry	SOP-MG-LAB.M.0051.6	Roche Cobas® 6000	x	
Urin acid	Serum EDTA plasma Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0032.5	Roche Cobas® 6000	x	
Urea	Serum EDTA plasma Li-Heparin plasma Urine	UV/VIS photometry	SOP-MG-LAB.M.0037.6	Roche Cobas® 6000	x	

**Type of examination:**

**Spectrometry - Reflectometry (carrier test methods) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Bilirubin	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Glucose	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Hemoglobin	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Ketone	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Leukocytes	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Nitrite	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
pH value	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Protein	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Specific weight	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	
Urobilinogen	Urine	Reflectance Photometry	SOP-MG-LAB.M.0081.3	Roche Cobas®u 411	x	

**Type of examination:**

**Spectrometry (Turbidimetry) \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Albumin	Urine Cerebrospinal fluid	Turbidimetry	SOP-MG-LAB.M.0085.7	Roche Cobas® 6000	x	
Protein total	Urine Cerebrospinal fluid	Turbidimetry	SOP-MG-LAB.M.0112.4	Roche Cobas® 6000	x	
Transferrin	Serum Li-Heparin plasma	Turbidimetry	SOP-MG-LAB.M.0107.5	Roche Cobas® 6000	x	

**Medical laboratory field: Virology**

**Type of examination:**

**Ligand assays \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
Hepatitis Bs antigen	Serum EDTA plasma Li-Heparin plasma Citrate plasma	ECLIA	SOP-MG-LAB.M.0065.6	Roche Cobas® 6000	x	
Hepatitis C antibodies	Serum EDTA plasma Heparin plasma Citrate plasma	ECLIA	SOP-MG-LAB.M.0066.6	Roche Cobas® 6000	x	
HIV-1/2 antibodies	Serum EDTA plasma Li-Heparin plasma	ECLIA	SOP-MG-LAB.M.0073.5	Roche Cobas® 6000	x	

**Type of examination:**

**Molecular genetic test methods and techniques \***

Analyte (measurement parameter)	Test material (matrix)	Test technique	QM Document	Analyzer	CE-method	in-house method
SARS-CoV-2	Nasal, pharyngeal and nasopharyngeal smear	Real-time PCR	SOP-MG-PCR.M.0004.2	Bio-Rad CFX96 Dx	x	