

DAkKS | Deutsche Akkreditierungsstelle GmbH
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Freiburg Medical Laboratory Middle East (L.L.C)
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DUBAI
VEREINIGTE ARABISCHE EMIRATE

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22.05.2023

Sehr geehrter Frau Dr. Jaksch,

anbei erhalten Sie Ihre Anlage und Urkunde.

Für Fragen stehen wir Ihnen gern zur Verfügung.

Mit freundlichen Grüßen
Im Auftrag

gez. Dr. Christina Wanka
Verfahrensmanagerin

Geschäftsführer:
Dr.-Ing. Stephan Finke

Vorsitzender des Aufsichtsrates:
Bernd Kowalski

Sitz: Berlin, AG Berlin-Charlotten-
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www.dakks.de

Accreditation

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

Freiburg Medical Laboratory Middle East (L.L.C)
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meets the requirements according to DIN EN ISO 15189:2014 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.

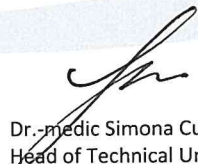
The management system requirements of DIN EN ISO 15189 are written in the language relevant to the operations of medical laboratories and confirm generally with the principles of DIN EN ISO 9001.

This accreditation was issued 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 with accreditation number D-ML-13455-01 is valid to 21.05.2028. It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 12 pages.

Registration number of the accreditation certificate: **D-ML-13455-01-00**

Berlin, 22.05.2023



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).

German Accreditation Body

Annex to the Accreditation Certificate D-ML-13455-01-00 according to DIN EN ISO 15189:2014

Period of validity: 22.05.2023 to 21.05.2028

Date of issue: 22.05.2023

Holder of accreditation certificate:

Freiburg Medical Laboratory, Middle East (L.L.C)

Sheikh Khalifa Bin Zayed Road

P.O. Box 3068

Dubai

VEREINIGTE ARABISCHE EMIRATE

The medical laboratory meets the requirements of DIN EN ISO 15189:2014 to carry out the conformity assessment activities listed in this annex. The medical 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 15189 are written in the language relevant to the operations of medical laboratories and confirm generally with the principles of DIN EN ISO 9001.

Tests in the field:

Medical Laboratory Diagnosis

Medical Analytical Fields:

Clinical Chemistry

Immunology

Humangenetics (Molecular Genetics)

Transfusion Medicine

Microbiology

Virology

The laboratory is permitted within the specified areas marked with* the free choice of standard or equivalent test Test techniques, without being required to inform and obtain prior approval from DAkkS.

The listed test Test techniques are exemplary. The laboratory maintains a current list of all test Test techniques in a flexible scope of accreditation.

This certificate annex 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 given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de>.

Medicinal Analytical field: Clinical Chemistry

Type of test:

Chromatography (High Pressure Liquid Chromatography (HPLC))*

Analyte (measurement parameter)	Test material (matrix)	Test technique
HbF	EDTA Blood	HPLC (IEC)
HbA1c	EDTA Blood	HPLC (IEC)
HbA2	EDTA Blood	HPLC (IEC)
HbD	EDTA Blood	HPLC (IEC)
HbS	EDTA Blood	HPLC (IEC)
HbC	EDTA Blood	HPLC (IEC)
HbA1c DCCT	EDTA Blood	HPLC
HbA1c IFCC	EDTA Blood	HPLC

Type of test:

Electrochemical tests*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chloride	Serum, Heparin Plasma, Urine	ISE
Potassium	Serum, Heparin Plasma, Urine	ISE
Sodium	Serum, Heparin Plasma, Urine	ISE

Type of test:

Flow cytometry*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential Blood Count	EDTA Blood	Flow cytometry
Hematocrit	EDTA Blood	RBC pulse height detection
Hemoglobin	EDTA Blood	SLS-Hemoglobin
Platelets	EDTA Blood	Hydro Dynamic Focusing
RBC Index MCH	EDTA Blood	Calculation
RBC Index MCHC	EDTA Blood	Calculation
RBC Index MCV	EDTA Blood	Calculation
Red Blood Cells	EDTA Blood	Hydro Dynamic Focusing
White Blood Cell Count	EDTA Blood	Flow cytometry

Type of Test:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ACTH	EDTA Plasma	ECLIA
AFP	Serum, Heparin Plasma, EDTA Plasma	ECLIA
AMH	Serum, Heparin Plasma	ECLIA
Bioavailable Testosterone	Serum, Heparin Plasma, EDTA Plasma	Calculation

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Analyte (measurement parameter)	Test material (matrix)	Test technique
CA 125	Serum, Heparin Plasma, EDTA Plasma	ECLIA
CA 15-3	Serum, Heparin Plasma, EDTA Plasma	ECLIA
CA 19-9	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Calprotectin	Stool	CLIA
Carbamazepine	Serum, Heparin Plasma, EDTA Plasma	MAIA
CEA	Serum, Heparin Plasma, EDTA Plasma	ECLIA
CK-MB	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Cortisol	Serum, Heparin Plasma, EDTA Plasma	ECLIA
DHEA-S	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Drug screening	Urine	IA
Estradiol	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Folate	Serum, Heparin Plasma	ECLIA
Free PSA	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Free PSA %	Serum	Calculation
Free T3	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Free T4	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Free Testosterone	Serum, Heparin Plasma, EDTA Plasma	Calculation
Free Testosterone	Serum, Heparin Plasma, EDTA Plasma	Calculation
FSH	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Haemoglobin	Stool	IA (Faecal Occult Blood)
HCG+Beta	Serum, Heparin Plasma, EDTA Plasma	ECLIA
HCG+Beta, free	Serum	ECLIA
Homa Index	Serum, Heparin Plasma, EDTA Plasma	Calculation
Insulin	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Interleukin-6	Serum, Heparin Plasma, EDTA Plasma	ECLIA

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Analyte (measurement parameter)	Test material (matrix)	Test technique
LH	Serum, Heparin Plasma, EDTA Plasma	ECLIA
NT-Pro BNP	Serum, Li-Heparin Plasma, Na-Heparin Plasma, EDTA plasma	ECLIA
PAPP-A	Serum	ECLIA
Progesterone	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Progesterone	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Prolactin	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Prolactin	Serum, Heparin Plasma, EDTA Plasma	ECLIA
PTH, intact	EDTA Plasma, Serum	ECLIA
SHBG	Serum, Li-Heparin Plasma	ECLIA
Testosterone	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Testosterone	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Thyroglobulin (TG)	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Total PSA	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Total T3	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Total T4	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Troponin T, high sensitive	Serum, Heparin Plasma, EDTA Plasma	ECLIA
TSH	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Valproic Acid	Serum, Heparin Plasma, EDTA Plasma	EIA
Vitamin B12	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Vitamin D (25OH)	Serum, Heparin Plasma, EDTA Plasma	ECLIA

Type of Test:
Microscopy

Analyte (measurement parameter)	Test material (matrix)	Test technique
Differential Blood Count (manual)	EDTA Blood, Smear	Microscopy
Urine sediment	Urine	Microscopy

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Type of Test:

Optical Clot Detection*

Analyte (measurement parameter)	Test material (matrix)	Test technique
aPTT	Citrated Plasma	Optical Clot Detection
Fibrinogen	Citrated Plasma	Optical Clot Detection
INR	Citrated Plasma	Calculation
Lupus Anticoagulants	Citrated Plasma	Optical Clot Detection
PT	Citrated Plasma	Optical Clot Detection

Type of Test:

Spectrometry (UV-VIS-Photometry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
Alkaline Phosphatase	Serum, Heparin Plasma	Photometry VIS
ALT	Serum, Heparin Plasma, EDTA Plasma	Photometry UV
Ammonia	EDTA Plasma	Photometry UV
Amylase	Serum, Heparin Plasma, Urine	Photometry VIS
AST	Serum, Heparin Plasma, EDTA Plasma	Photometry UV
Bicarbonate	Serum	Photometry VIS
Bilirubin direct	Serum, Heparin Plasma	Photometry VIS
Bilirubin total	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
BUN/Creatinine ratio	Serum, Heparin Plasma, EDTA Plasma	Calculation
BUN/Urea	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry UV
Calcium	Serum, Heparin Plasma, Urine	Photometry UV
Cholesterol	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
Cholinesterase	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
CK	Serum, Heparin Plasma, EDTA Plasma	Photometry UV
Creatinine	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry VIS
Ethanol	Serum, EDTA Plasma, Urine	Photometry UV
G6PDH	EDTA Blood	Photometry UV
GGT	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
Glucose	NaF Plasma, Serum, Heparin Plasma, EDTA Plasma, CSF, Urine	Photometry UV

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Analyte (measurement parameter)	Test material (matrix)	Test technique
HDL-Cholesterol	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
Homocysteine	EDTA plasma, Heparin Plasma, Serum	Photometry UV
Iron	Serum, Heparin Plasma	Photometry VIS
Lactate	NaF Plasma, CSF	Photometry VIS
LDH	Serum, Heparin Plasma, EDTA Plasma	Photometry UV
LDL Friedewald	Serum, Heparin Plasma	Calculation
LDL-Cholesterol	Serum, Heparin Plasma	Photometry VIS
Lipase	Serum, Heparin Plasma	Photometry VIS
Magnesium	Serum, Heparin Plasma, Urine	Photometry VIS
Pancreatic Amylase	Serum, Heparin Plasma	Photometry VIS
Phosphorus	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry UV
Protein	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
Protein	Urine, CSF	Photometry VIS
Triglycerides	Serum, Heparin Plasma, EDTA Plasma	Photometry VIS
UIBC	Serum, Heparin Plasma	Photometry VIS
Uric acid	Serum, Heparin Plasma, EDTA Plasma, Urine	Photometry VIS
Zinc	Serum	Photometry VIS

Type of Test:

Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Albumin	Urine, CSF	Turbidimetry
Albumin/Creatinine Ratio	Urine	Calculation
Antistreptolysin O	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Apolipoprotein A1	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
CRP	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
CRP HS	Serum, Heparin Plasma	Turbidimetry
Cystatin C	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
D-Dimer	Citrated Plasma	Turbidimetry
Estimated Average Glucose	EDTA Blood	Calculation
Ferritin	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Glomerular Filtration Rate/GFR	Serum, Heparin Plasma, EDTA Plasma	Calculation
Haptoglobin	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Lipoprotein (a)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Rheumatoid Factor	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Total Protein/Creatinine Ratio	Urine	Calculation
Transferrin	Serum, Heparin Plasma	Turbidimetry

Medicinal Analytical field: Immunology

Type of test:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ANA Profile	Serum	Immunoblot
Anti-TG	Serum, EDTA Plasma	ECLIA
Anti-TPO	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Atopy Allergy Screening	Serum	Immunoblot
Cardiolipin IgG	Serum	EIA
Cardiolipin IgM	Serum	EIA
CCP Abs	Serum	EIA
dsDNA/Nucleosomes Abs	Serum	EIA
Food Allergy Screening	Serum	Immunoblot
IgE, total	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Phospholipid IgG	Serum	EIA
Phospholipid IgM	Serum	EIA
Respiratory Allergy Screening	Serum	Immunoblot
Tissue Transglutaminase IgA	Serum	EIA
Tissue Transglutaminase IgG	Serum	EIA

Type of Test:

Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
AMA/M2/LKM	Serum	IFT
ANA/ASMA type Actin	Serum	IFT
ANCA (cANCA, pANCA)	Serum	IFT
Endomysium IgA	Serum	IFT
Gliadin IgA	Serum	IFT

Type of Test:

Spectrometry (Turbidimetry)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Complement C3c	Serum, Heparin Plasma	Turbidimetry
Complement C4	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Immunoglobulin A (IgA)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Immunoglobulin G (IgA)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry
Immunoglobulin M (IgA)	Serum, Heparin Plasma, EDTA Plasma	Turbidimetry

Medicinal Analytical field: Humangenetics (Molecular Genetics)

Type of test:

Molecular Biological Test techniques (Amplification Test technique)

Analyte (measurement parameter)	Test material (matrix)	Test technique
HLA-B27	EDTA blood	PCR Microarray
Factor V	EDTA blood	PCR Microarray
Factor II	EDTA blood	PCR Microarray
MTHFR	EDTA blood	PCR Microarray

Medicinal Analytical field: Microbiology

Type of test:

Agglutination

Analyte (measurement parameter)	Test material (matrix)	Test technique
Streptococci	Culture	Agglutination
TPHA	Serum	Agglutination

Type of test:

Ligand assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Interferon gamma Stimulation test (for indirect testing of Mycobacter tuberculosis)	EDTA Blood	CLIA
Mycoplasma pneumoniae IgA	Serum	EIA
Mycoplasma pneumoniae IgG	Serum	EIA
Mycoplasma pneumoniae IgM	Serum	EIA

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Analyte (measurement parameter)	Test material (matrix)	Test technique
Toxoplasma IgG	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Toxoplasma IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA

Type of test:

Chromatography (Immunochromography)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Helicobacter Pylori Ag	Stool	Immunochromatography

Type of test:

Susceptibility (resistance) testing*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic Bacteria	Culture	Disc diffusion test
Anaerobic Bacteria	Culture	Disc diffusion test

Type of test:

Differentiation/Identification/Typing*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic Bacteria	Culture	Microscopy / Biochemical / Culture
Anaerobic Bacteria	Culture	Microscopy / Biochemical / Culture
Corynebacterium species	Culture	Microscopy / Culture
Enterobacteriaceae	Culture	Microscopy / Biochemical / Culture
Gardnerella vaginalis	Culture	Microscopy / Culture
Haemophilus	Culture	Microscopy / Biochemical / Culture
Lactobacillus	Culture	Microscopy / Biochemical / Culture
MRSA	Culture	Microscopy / Biochemical / Culture
Neisseria gonorrhoeae	Culture	Microscopy / Biochemical / Culture
Non-fermenter	Culture	Microscopy / Biochemical / Culture
Staphylococci	Culture	Microscopy / Biochemical / Culture
Streptococci	Culture	Microscopy / Biochemical / Culture
Yeast (Candida)	Culture	Microscopy / Biochemical / Culture

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Type of test:

Culture*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Aerobic Bacteria	Urine, Genital Tract Test material (matrix), Body fluids, Deep wound, Pus, Abscess, Stool, Throat swab, Nasal swab, Ear swab, Eye swab, Skin swab, Sputum	Culture
Anaerobic Bacteria	Genital Tract Test material (matrix), Body fluids, Deep wound, Pus, Abscess	Culture
Campylobacter, Salmonella, Shigella	Stool	Culture

Type of Test:

Molecular Biological Test techniques (Amplification Test technique)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Chlamydia trachomatis	Thinprep, swab, urine	multiplex real-time PCR assay
Neisseria gonorrhoeae	Thinprep, swab, urine	multiplex real-time PCR assay
Mycoplasma genitalium	Thinprep, swab, urine	multiplex real-time PCR assay
Mycoplasma hominis	Thinprep, swab, urine	multiplex real-time PCR assay
Treponema pallidum	Thinprep, swab, urine	multiplex real-time PCR assay
Treponema vaginalis	Thinprep, swab, urine	multiplex real-time PCR assay
Ureaplasma parvum	Thinprep, swab, urine	multiplex real-time PCR assay
Ureaplasma urealyticum	Thinprep, swab, urine	multiplex real-time PCR assay

Medicinal Analytical field: Virology

Type of test:

Ligand Assays*

Analyte (measurement parameter)	Test material (matrix)	Test technique
Anti-HBe	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Anti-HAV	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Anti-HAV IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Anti-HBc	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Anti-HBs	Serum, EDTA Plasma	ECLIA
CMV Abs IgG	Serum, Heparin Plasma, EDTA Plasma	ECLIA

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Analyte (measurement parameter)	Test material (matrix)	Test technique
CMV ABS IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA
HBe Ag	Serum, Heparin Plasma, EDTA Plasma	ECLIA
HBs Ag	Serum, Heparin Plasma, EDTA Plasma	ECLIA
HCV Abs	Serum, Heparin Plasma, EDTA Plasma	ECLIA
HIV combi	Serum, Heparin Plasma, EDTA Plasma	ECLIA
HSV 1 IgG	Serum	EIA
HSV 1 IgM	Serum	EIA
HSV 2 IgG	Serum	EIA
HSV 2 IgM	Serum	EIA
Rubella IgG	Serum, Heparin Plasma, EDTA Plasma	ECLIA
Rubella IgM	Serum, Heparin Plasma, EDTA Plasma	ECLIA

Type of Test:
Microscopy*

Analyte (measurement parameter)	Test material (matrix)	Test technique
EBNA	Serum	IFT
EBV-CA-IgG	Serum	IFT
EBV-CA-IgM	Serum	IFT
EBV-EA-IgG	Serum	IFT

Type of Test:
Molecular Biological Test techniques (Amplification Test technique)*

Analyte (measurement parameter)	Test material (matrix)	Test technique
CMV DNA	Thinprep, swab, urine	multiplex real-time PCR assay
HPV	LBC, Swab	Real-Time PCR
HSV1 DNA	Thinprep, swab, urine	multiplex real-time PCR assay
HSV2 DNA	Thinprep, swab, urine	multiplex real-time PCR assay
Sars-CoV-2 RNA	Swab	Real-Time PCR

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Medicinal Analytical field: Transfusion Medicine

Type of test:

Agglutination*

Analyte (measurement parameter)	Test material (matrix)	Test technique
ABO/Rh Blood Group + Reverse Grouping	EDTA Blood, Serum	Agglutination
Coombs Test, direct	EDTA Blood	Agglutination
Coombs Test, indirect	Serum, EDTA Plasma	Agglutination
Rh Subgroups and Kell	EDTA Blood	Agglutination