CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

SC HEMAT-ROM SRL dba HEMATROM-IC

Intrarea Tintea Nr. 6,
Bucuresti, Romania
(and satellite location as shown on the scope)

Fulfills the requirements of

ISO/IEC 17043:2010

In the field of

PROFICIENCY TESTING PROVIDER

This certificate is valid only when accompanied by a current scope of accreditation document.
The current scope of accreditation can be verified at www.anab.org.

Jason Stine, Vice President

Expiry Date: 14 December 2025

Certificate Number: AP-3047

This proficiency testing provider is accredited in accordance with the recognized International Standard ISO/IEC 17043:2010. This accreditation demonstrates technical competence for a defined scope and the operation of a proficiency testing provider quality management system.

SCOPE OF ACCREDITATION TO ISO/IEC 17043:2010

SC HEMAT-ROM SRL dba
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PROFICIENCY TEST PROVIDER

Valid to: **December 14, 2025** Certificate Number: **AP-3047**

Medical: Biochemistry

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Clinical Chemistry (Code CC)	Amylase, Creatine kinase, Alkaline Phosphatase, GGT, LDH, Lipase, TGO/AST, TGP/ALT, Cholinesterase, Uric Acid, Albumin, Direct Bilirubin, Total Bilirubin, Calcium, Ionic Calcium, Chlorine, Total Cholesterol, HDL Cholesterol, LDL Cholesterol, Creatinine, Iron, Inorganic Phosphorus, Glucose, Magnesium Potassium, Lithium, Copper, Total Protein, Sodium, Pancreatic Amylase, Zinc, Triglycerides, Urea, Total Iron Binding Capacity, Total Lipids, Bicarbonate	Serum/plasma	Consensus Value
Urine Chemistry (Code CU)	Amylase, Uric Acid, Calcium, Chloride, Creatinine, Inorganic Phosphorus, Glucose, Magnesium, Microalbuminuria, Potassium, Total Protein, Sodium, Urea, Osmolality	Urine	Consensus Value
Urine Chemistry – Qualitative (Code SS)	Glucose, Ketones, Total Protein, Urobilinogen, Bilirubin, Nitrites, Leukocytes, Erythrocytes, pH, Ascorbic Acid, Density Microscopic Examination	Urine	Consensus Value

Medical: Biochemistry

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Protein Electrophoresis (Code EL)	Albumin, α1-Globulin, α2-Globulin, ß-Globulin, ß1-Globulin, ß2-Globulin, Ɣ-Globulin	Serum	Consensus Value
Haemoglobin A1c (Code HG)	HbA1c	Blood with human and simulated cells	Consensus Value
Myocardial Markers (Code MC)	CK-MB, Homocysteine, Myoglobin, NT-proBNP, proBNP, Troponin-I, Troponin-T, D-Dimer, hs-CRP	Serum/plasma	Consensus Value

Medical: Hematology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Reticulocyte Count (Code RE)	Reticulocyte Count	Blood with human and simulated cells	Consensus Value
Blood Cell Count 3-Diff (Code HE)	WBC, RBC, HGB, HCT, MCV, PLT, MCH, MCHC, RDW-CV, RDW-SD, MPV, PCT, PDW-CV, PDW-SD	Blood with human and simulated cells	Consensus Value
Blood Cell Count 5-Diff (Code SY)	WBC, NEUT#, NEUT%, LYMP#, LYMP%, MONO#, MONO%, EOS#, EOS%, BASO#, BASO%, RBC, HGB, HCT, MCV, PLT, MCH, MCHC, RDW-CV, RDW-SD, MPV, PCT, PDW-CV, PDW-SD	Blood with human and simulated cells	Consensus Value
Cytological Examination of the Blood Smear (Code FL)	Identification of Cellular Elements and Diagnosis	Virtual image	Consensus Value related to Reference Value
ESR (Code VS)	Erythrocyte Sedimentation Rate	Suspension with red blood cells	Consensus Value
ESR – Alifax Analyzers (Code VSX)	Erythrocyte Sedimentation Rate	Latex	Consensus Value
ABO and RH Grouping (Code IM)	ABO and RH Interpretation	Suspension with red blood cells	Consensus Value related to Reference Value
Anti-Rh Antibodies (Code RH)	Determination of the Presence of Specific Anti-Rh Antibodies. Anti-Rh Antibody Titer	Serum	Consensus Value related to Reference Value

Medical: Hematology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Phenotype – Human Blood (Code RK)	ABO Blood Grouping and Rh Interpretation, Anti-A, Anti-B, Anti-D, Rh Systems: Kell Antigen, Rh-phenotyping, Direct Coombs Testing	Suspension with red blood cells	Consensus Value related to Reference Value
Indirect Coomb's Test (Code CI)	ABO Blood Grouping Interpretation, Irregular Antibody Screening, DAI, Compatibility Testing	serum	Consensus Value related to Reference Value
Coagulation (Code CO)	Prothrombin Time (PT), INR, PT%, APTT, APTT Ratio, Fibrinogen	Plasma	Consensus Value

Medical: Immunology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Hormones (Code HO)	T3, FT3, T4, FT4, TSH, FSH, β-HCG, Insulin, Cortisol, Folic acid, Vitamin B12, Ferritin, DHEA, STH, HGH, Digoxin, Anti-TPO, LH, Progesterone, Testosterone, Estradiol, Prolactin, Total HCG, Aldosterone	Serum/plasma	Consensus Value
Tumour Markers (Code MT)	CEA, AFP, PSA (total), PSA (free), CA 19-9, CA 15-3, CA125, AFP	Serum/plasma	Consensus Value
Proteins (Code PS)	Total Protein, CRP, ASLO, RF, C3, C4, IgA, IgG, IgE, IgM, Alpha 1-Antitrypsin, Alpha 2 – Macroglobulin, Beta2 - Microglobulin, Haptoglobin, Transferrin, Albumin, Ceruloplasmin, Ferritin	Serum	Consensus Value
Special Immunology (Code IS)	Vitamin D, Anti-TG, Anti-TPO, Osteocalcin, Parathormone, Procalcitonin, ACTH, C-Peptide, 17-OH Progesterone	Serum	Consensus Value
SARS-CoV-2, Nucleic Acid Detection (Code COV)	SARS-CoV-2 RNA and Diagnosis of COVID-19	Suspension with recombinant virus particles	Consensus Value related to Reference Value
Hepatitis A (Code HA)	Anti - HAV IgM, Anti-HAV IgG, Anti -HAV Total (IgG+IgM)	Serum/plasma	Consensus Value related to Reference Value

Medical: Immunology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Hepatitis B (Code HB)	HBsAg, Anti-HBs, Anti-HBc IgM, Anti-HBc Total (IgG+IgM), HBeAg, Anti-HBe	Serum/plasma	Consensus Value related to Reference Value
Hepatitis C (Code HC)	Anti-HCV	Serum/plasma	Consensus Value related to Reference Value
HIV (Code HV)	Anti-HIV	Serum/plasma	Consensus Value related to Reference Value
Syphilis (Code SF)	RPR, VDRL, TPHA, Treponema Pallidum Antibodies, FTA-ABS	Serum/plasma	Consensus Value related to Reference Value
Torch (Code IF)	Anti-Toxoplasma IgG, Anti-Toxoplasma IgM, Anti-Toxoplasma Total (IgG+IgM), Anti-CMV IgG, Anti-CMV IgM, Anti-CMV Total (IgG+IgM), Anti-Rubella IgG, Anti-Rubella IgM, Anti-Rubella Total (IgG+IgM), Anti-HSV 1 IgG, Anti-HSV 1 IgM, Anti-HSV 2 IgG, Anti-HSV 2 IgM, Anti-HSV ½ IgG, Anti-HSV ½ IgM	Serum/plasma	Consensus Value related to Reference Value
Helicobacter pylori Antibodies (Code HP)	Helicobacter pylori IgG (qualitative and quantitative)	Serum/plasma	Consensus Value related to Reference Value
Chlamydia trachomatis Antibodies (Code CH)	Antibodies Chlamydia trachomatis	Serum/plasma	Consensus Value related to Reference Value
Helicobacter pylori Antigen (Code AG)	Helicobacter pylori- Antigen Detection	Suspension/ Buffer solution which may contain or not helicobacter pylori antigen	Consensus Value related to Reference Value
Chlamydia trachomatis Antigen (Code CHX)	Chlamydia trachomatis- Antigen Detection	Urine	Consensus Value related to Reference Value
Giardia Antigen (Code GI)	Giardia – Antigen Detection	Suspension/ Buffer solution which may contain or not giardia antigen	Consensus Value related to Reference Value
Faecal Occult Blood (Code HF)	Detection of Hemoglobin	Suspension/buffer solution which may contain or not hemoglobin	Consensus Value related to Reference Value

Medical: Bacteriology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
General Bacteriology (Code BA)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing.	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Urine Culture (Code UR)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Faecal Culture (Code CP)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology - Throat Culture (Code EX)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology - Vaginal Culture (Code SV)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Urethral Culture (Code SU)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Ear Culture (Code SO)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Nose Culture (Code SN)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Conjunctival Culture (Code SC)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Purulent Culture (Code SP)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value

Medical: Bacteriology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Bacteriology – Punction Liquid (Code LP)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Sputum (Code SA)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology – Blood Culture (Code MO)	Microscopic Examination, Culture and Identification of Aerobic Microbes Antimicrobial Susceptibility Testing	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Bacteriology - Screening for multi-drug resistant bacteria (Code BS)	Microscopic Examination, Culture and Identification of Aerobic Microbes	Bacterial cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Microbial Smear, Gram Staining, and Microscopy (Code FM)	Identification of Pathogenic Cultures	Virtual image	Consensus Value related to Reference Value

Medical: Mycology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
General Mycology (Code MI)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Urine Culture (Code URX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Faecal Culture (Code CPX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology - Throat Culture (Code EXX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value

Medical: Mycology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Mycology - Vaginal Culture (Code SVX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Urethral Culture (Code SUX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Ear Culture (Code SOX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Nose Culture (Code SNX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Conjunctival Culture (Code SCX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Purulent Culture (Code SPX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Punction Liquid (Code LPX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Sputum (Code SAX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value
Mycology – Blood Culture (Code MOX)	Microscopic Examination, Culture and Identification Antimicrobial Susceptibility Testing of Yeast	Yeast cultures traceable to a collection of reference, with clinical significance	Consensus Value related to Reference Value

Medical: Parasitology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Parasites In Faeces (Code PF)	Screening and Identification of Intestinal Parasites	Virtual image	Consensus Value related to Reference Value

Medical: Gynecological Cytology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Gynecological Cytology – From the Method Babes Papanicolaou Smear (Code PA)	Diagnoses to the Bethesda System	Virtual image	Expert Consensus

Medical: Histopathology

Description of Item	Properties Measured	Range of Property	Procedure for Establishing Assigned Value
Hematoxilyn-Eosin stain (code HHE)	HE stain and diagnose	Slides	Expert Consensus
Hematoxilyn-Eosin and special stains (code HHS)	HE stain, special stains and diagnose	Slides	Expert Consensus
Immunohistochemistry (Code HIH)	HE stain, immunohistochemical markers and diagnose	Slides	Expert Consensus

Note:

1. This scope is formatted as part of a single document including Certificate of Accreditation No. AP-3047.
2. PT Production occurs at the satellite site location.

Jason Stine, Vice President