

MEDICAL LABORATORY ACCREDITATION PROGRAM

Scope of Accreditation

Legal Name of Accredited Laboratory: Département clinique de médecine de

laboratoire du Centre hospitalier de l'Université de Montréal (CHUM) (Site Institut de cardiologie de Montréal)

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SCC File Number:	151138
Provider:	BNQ-EL
Provider File Number:	56667-1
Accreditation Standard(s):	ISO 15189:2012 Medical laboratories – Requirements for quality and competence ISO 22870:2016 Point of care testing (POCT) – Requirements for quality and competence CAN/CSA-Z902-20 Blood and blood components
Program Specialty Area:	Medical
Initial Accreditation:	2021-03-25
Most Recent Accreditation:	2023-11-16
Accreditation Valid to:	2025-03-25

Remarque: La présente portée d'accréditation existe également en français, celle-ci est publiée séparément. Note: This scope of accreditation is also available in French as a separately issued document.



SCC Group Accreditation:

This laboratory is a part of a Group Accreditation with the following facilities in accordance with SCC's policy on Group Accreditation documented in the Accreditation Services Accreditation Program Overview.

- Centre hospitalier de l'Université de Montréal, 1051, Sanguinet St., Montréal (Québec) H2X 3E4 (CCN no.: 151126 / BNQ no.: 56655-1)
- Hôpital Maisonneuve-Rosemont, 5415, de l'Assomption Blvd., Montréal (Québec) H1T 2M4 (CCN no.: 151128 / BNQ no.: 56657-1)
- Hôpital Santa Cabrini, 5655, Saint-Zotique E. St., Montréal (Québec) H1T 1P7 (CCN no.: 151129 / BNQ no.: 56658-1)
- Hôpital de Verdun, 4000, Lasalle Blvd., Montréal (Québec) H4G 2A3 (CCN no.: 151132 / BNQ no.: 56661-1)
- Hôpital Notre-Dame, 1560, Sherbrooke E. St., Montréal (Québec) H2L 4M1 (CCN no.: 151133 / BNQ no.: 56662-1)
- Hôpital du Sacré-Cœur de Montréal, 5400, Gouin W. Blvd., Montréal (Québec) H4J 1C5 (CCN no.: 151134 / BNQ no.: 56663-1)
- Hôpital Fleury, 2180, Fleury E. St., Montréal (Québec) H2B 1K3 (CCN no.: 151135 / BNQ no.: 56664-1)
- Hôpital Jean-Talon, 1385, Jean-Talon E. St., Montréal (Québec) H2E 1S6 (CCN no.: 151136 / BNQ no.: 56665-1)

SCOPE OF ACCREDITATION

01.0 BIOCHEMISTRY*

- 01.1 BIOCHEMISTRY CLINICAL01.2 BIOCHEMISTRY HORMONAL
- 01.4 BIOCHEMISTRY MEDICATION
- 01.5 BIOCHEMISTRY TOXICOLOGY
- (*) This discipline covers tests subject to ISO 22870; see detailed scope.

02.0 MOLECULAR BIOLOGY

02.3 MOLECULAR DIAGNOSIS – INFECTIOUS DISEASES

05.0 HEMATOLOGY

- 05.2 HEMATOLOGY CYTOLOGY
- 05.5 HEMATOLOGY HEMOSTASIS
- 05.7 HEMATOLOGY IMMUNOLOGY

06.0 TRANSFUSION MEDICINE

07.0 MICROBIOLOGY

07.1 MICROBIOLOGY – BACTERIOLOGY



SCOPE OF ACCREDITATION

07.2	MICROBIOLOGY - IMMUNOSEROLOGY
07.3	MICROBIOLOGY - MYCOBACTERIOLOGY
07.4	MICROBIOLOGY - MYCOLOGY
07.5	MICROBIOLOGY - PARASITOLOGY

08.0 ANATOMICAL PATHOLOGY

08.1 PATHOLOGY – CLINICAL

DETAILS OF SCOPE OF ACCREDITATION

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30009 - Folic acid (folates)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30013 - Uric Acid	Spectrophotometry	Blood and derived products, urine, other biological fluids
		30016 - Alanine aminotransferase (ALT)	Spectrophotometry	Blood and derived products
		30017 - Albumin	Spectrophotometry	Blood and derived products, other biological fluids
		30030 - Total amylase	Spectrophotometry	Blood and derived products, urine, other biological fluids
	01.1 Biochemistry – clinical	30039 - Prostate-specific antigen (PSA) test	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
O1 O DIOCUENISTRY		30052 - Apolipoprotein Al	Nephelometry	Blood and derived products
01.0 BIOCHEMISTRY		30054 - Apolipoprotein B	Nephelometry	Blood and derived products
		30060 - Aspartate aminotransferase (AST)	Spectrophotometry	Blood and derived products
		30076 - Lactate acid (by specific electrode)	Electrochemistry	Blood and derived products
		30078 - Procalcitonin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30083 - Bilirubin Direct (conjugated)	Spectrophotometry	Blood and derived products
		30084 - Bilirubin total	Spectrophotometry	Blood and derived products, other biological fluids
		30095 - NT-PRO-BNP (Brain Natriuretic Peptide)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products



Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30105 - Calcium total	Spectrophotometry	Blood and derived products, urine
		30106 - Calcium Ionized	Electrochemistry	Blood and derived products
		30115 - Chloride	Electrochemistry	Blood and derived products, urine
		30116 - Cholesterol - HDL	Spectrophotometry	Blood and derived products
		30119 - Cholesterol total	Spectrophotometry	Blood and derived products, other biological fluids
		30117 - Cholesterol – LDL (measured)	Spectrophotometry	Blood and derived products
		30123 - CK-MB mass	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30124 - Total CO2 or	Electrochemistry	Dlood and derived are dusts
		bicarbonate (dosage only)	Calculation	Blood and derived products
		30130 - CK total	Spectrophotometry	Blood and derived products
		30132 - Creatinine	Spectrophotometry	Blood and derived products, urine
		30153 - Single refractometric density (excl. strips)	Refractometry	Urine
		30191 - Iron (serum)	Spectrophotometry	Blood and derived products
		30193 - Ferritin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30210 - Gamma glutamyl transferase (GGT)	Spectrophotometry	Blood and derived products
		30212 - Blood Gas (pO2,	Electrochemistry	
		pCO2, pH, HCO3, COHb, metHb, oxyHb, SulfHb)	Co-oximetry	Blood and derived products
		20244 Classes	Spectrophotometry	Blood and derived products,
		30214 - Glucose	Electrochemistry	CSF
		30235 - Homocystein (immuno-enzymatic)	Nephelometry	Blood and derived products
		30248 - Glycated hemoglobin (HbA1c)	Immunoassay - turbidimetry	Blood and derived products
		30273 - Immunoglobulin IgA	Nephelometry	Blood and derived products
		30277 - Immunoglobulin IgG	Nephelometry	Blood and derived products
		30279 - Immunoglobulin IgM	Nephelometry	Blood and derived products
		30301 - Lactate Dehydrogenase (LD)	Spectrophotometry	Blood and derived products, other biological fluids
		30306 - Triglyceride lipase	Spectrophotometry	Blood and derived products





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30332 - Total magnesium	Spectrophotometry	Blood and derived products, urine
		20227 Minorally and Arica	Nephelometry	11.2
		30337 - Microalbumin (urine)	Calculation	Urine
		30362 - Osmolality	Cryoscopic Osmometry	Blood and derived products, urine
		30383 - pH (biological fluid)	Electrochemistry	Other biological fluids
		30386 - Alkaline Phosphatase	Spectrophotometry	Blood and derived products
		30391 - Phosphate	Spectrophotometry	Blood and derived products, urine
		30398 - Potassium	Electrochemistry	Blood and derived products, urine
		30404 - Total protein (other fluids)	Spectrophotometry	Urine, CSF
		30405 - Total protein (serum)	Spectrophotometry	Blood and derived products
		30412 - C-reactive Protein (CRP) (including ultrasensitive)	Nephelometry	Blood and derived products
		30470 - Blood in biological fluids (qualitative)	Immunochromatography	Other biological fluids
		30471 - Occult Blood Stool (qualitative)	Immunochromatography	Feces
		30478 - Sodium	Electrochemistry	Blood and derived products, urine
		30511 - Transferrin	Nephelometry	Blood and derived products
		30512 - Triglycerides	Spectrophotometry	Blood and derived products
		30513 - Troponin T or I	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30531 - Urea	Spectrophotometry	Blood and derived products, urine
		30532 - Urine (microscopic exam)	Microscopic examination including preparation	Urine
		30533 - Urine (summary examination)	Reflectance	Urine
		30553 - Vitamin B12	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	01.2 Biochemistry –	30128 - Serum or urine cortisol without extraction	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	hormonal	30241 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (qualitative)	Chromatography	Blood and derived products, urine





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30242 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (quantitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30283 - Insulin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30502 - T4L (free thyroxine)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30516 - TSH (thyrotropic hormone)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30640 - Digoxin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	01.4 Biochemistry – medication	30671 - Gentamicin	Immunoassay - turbidimetry	Blood and derived products
	medication	30773 - Tobramycin (Nebcin®, Tobrex®)	Immunoassay - turbidimetry	Blood and derived products
		30780 - Vancomycin	Immunoassay - turbidimetry	Blood and derived products
	01.5 Biochemistry – toxicology	30851 - Street drugs / strip / drug	Immunoassay - fluorescence	Urine
	POCT	Capillary glucose determination		
		Prothrombin time measurement (INR) (Coagulometer)		
		Blood gas analysis with or without co-oximetry (pO2, pCO2, pH, HCO3, COHb, meHb, oxyHb, SulfHb, total CO2)	NA	Blood and derived products, secretions
		SARS-CoV-2 detection		
		Influenza A and B detection		
		40018 - Carbapenemase (NAAT)	Detection of nucleic acids	Clinical sample
02.0 MOLECULAR BIOLOGY	O2.3 Molecular diagnosis – infectious diseases	45026 - Clostridium difficile (toxin B gene) (NAAT) on clinical specimen	Detection of nucleic acids	Clinical sample
		45033 - Coronavirus (SARS- CoV-2); detection (NAAT) (rapid test, certified kit) on clinical sample	Detection of nucleic acids	Clinical sample
		45036 - Vancomycin-resistant Enterococcus (VRE) (NAAT) on clinical specimen	Detection of nucleic acids	Clinical sample





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		45100 - Methicillin-resistant Staphylococcus aureus (MRSA); detection (NAAT) on clinical specimen	Detection of nucleic acids	Clinical sample
		45051 - Coronavirus (SARS- CoV-2), Influenza A and B and RSV; detection (NAAT) (multiplex) (certified kit) on clinical specimen	Detection of nucleic acids	Clinical sample
		45055 - Coronavirus (SARS- CoV-2) and respiratory viruses; multiplex detection of 8 to 23 viruses (NAAT) (multiplex) (certified kit) on clinical specimen	Detection of nucleic acids	Clinical sample
		20321 - Fluid cytology with	Microscopic examination including preparation	Other biological fluids
		cytospin	Impedance measurement	
	05.2 Hematology – cytology	20342- Eosinophils (nasal secretions or urine)	Microscopic examination including preparation	Urine
		20361 - Complete blood count (CBC) or automated Hgb-HCT- Plat.	Flow cytometry	
			Impedance measurement	Blood and derived products, other biological fluids
			Calculation	
		20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	Blood and derived products
		20363 - Evaluation of red blood cells and platelets (orientation smear) (including staining)	Microscopic examination including preparation	Blood and derived products
05.0 HEMATOLOGY		20381 - Automated sedimentation	Precipitation	Blood and derived products
		20450 - Platelet (blood) (manual)	Microscopic examination including preparation	Blood and derived products
		20470 0 11 1	Impedance measurement	
		20470 - Reticulocytes (automated)	Flow cytometry	Blood and derived products
			Calculation	
		20014 - Antithrombin (activity)	Chromogenic method	Blood and derived products
		20044 - Cryofibrinogen	Visual reading	Blood and derived products
	05.5 Hematology –		Precipitation	, 22 22 2.2 ea p. eadets
	hemostasis	20060 - D-Dimer (semi- quantitative or qualitative or on slide)	Qualitative or quantitative agglutination	Blood and derived products
		20062 - D-Dimer (automated)	Aggregometry	Blood and derived products





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		20080 - Coagulation factor (II, V, VII, VIII, IX, X, XI and XII) (activity)	Chromogenic method	Blood and derived products
		20102 - Fibrinogen (activity)	Coagulometry	Blood and derived products
		20106 - Factor XIII (solubility test)	Turbidimetry	Blood and derived products
		20130 - Anti-Xa Heparin	Chromogenic method	Blood and derived products
		20240 - Activated partial thromboplastin time (APTT) or trhombin time (TT) or prothrombin time (PT)	Coagulometry	Blood and derived products
		20241 - Activated partial thromboplastin time or partial thromboplastin time + activator (APTT)	Coagulometry	Blood and derived products
		20242 - Partial thromboplastin time (PTT) after heparin neutralization	Coagulometry	Blood and derived products
		20243 - Prothrombin time (INR) including fibrinogen derivative	Coagulometry	Blood and derived products
		20248 - Thrombin time (TT)	Turbidimetry	Blood and derived products
		20252 - Diluted tissue thromboplastin inhibition test	Turbidimetry	Blood and derived products
		20254 – Thrombo- elastography	Coagulometry	Blood and derived products
		20011 - Anti-heparin-FP4 (ELISA)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		20390 - Haptoglobin	Nephelometry	Blood and derived products
	05.7 Hematology – immunology	20717 - Antinuclear (ANA) (immunofluorescence screening) (per dilution)	Immunoassay - fluorescence	Blood and derived products
		20774 - Cryoglobulins	Visual reading	Pland and darived products
		(qualitative)	Precipitation	Blood and derived products
	06.0 Transfusion medicine	10000 - Cold agglutinins (screening) (qualitative) including autocontrols	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE		10002 - Cold agglutinins (titration) (quantitative) (autocontrols included)	Immunological method of hemagglutination and derivative	Blood and derived products
		10007 - Irregular antibodies (manual identification)	Immunological method of hemagglutination and derivative	Blood and derived products





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		10024 - Compatibility (manual or automated)	Immunological method of hemagglutination and derivative	Blood and derived products
		10032 - Multispecific or monospecific direct coombs (tube technique) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
		10060 - Elution (including identification on eluate)	Immunological method of hemagglutination and derivative	Blood and derived products
		10086 - ABO-Rh blood type (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
		10136 - Common erythrocyte phenotype (patient or product / by antigen / excluding ABO, D / including controls) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
		10137 - Rare erythrocyte phenotype (patient or product / by antigen / including controls) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
		10150 - Irregular antibodies (manual search)	Immunological method of hemagglutination and derivative	Blood and derived products
		10170 - Antibody titration (per antibody) (including titration on previous serum)	Immunological method of hemagglutination and derivative	Blood and derived products
		10173 - Cell treatment (EGA KIT method)	Enzymatic method	Blood and derived products
		40020 - Multi-resistant gram- negative bacteria (bêta- lactamase-ESBL, carbapenemase) (screening)	Bacterial culture	Clinical sample, feces, secretions
	, 07.1 Microbiology – bacteriology	40026 - Bronchoscopy (semi- quantitative culture)	Bacterial culture	Clinical sample, secretions
07.0 MICROBIOLOGY		40047 - Minimum inhibitory concentration (MIC) microplate/automated card (per bacterium)	Phenotypic determination: sensitivity tests	Isolate
		40048 - Minimum inhibitory concentration (MIC) (strip) (per antibiotic and per bacterium)	Phenotypic determination: sensitivity tests	Isolate
		40049 - Catheter (semiquantitative culture)	Bacterial culture	Clinical sample
		40063 - Vancomycin-resistant Enterococcus (VRE) (specific culture)	Bacterial culture	Clinical sample, feces



Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		40065 - Expectorations (bacteriology) (includes	Microscopic examination including preparation	Clinical sample, secretions
		specimen rejected after Gram)	Bacterial culture	
		40080 - Throat (Strepto A, C, G or beta-hemolytic)	Bacterial culture	Clinical sample, secretions
		40102 - Blood culture (2 bottles: aerobic + anaerobic)	Bacterial culture	Blood and derived products
		40126 - Identification of a micro-organism to genus and/or species (identification cards on automated systems such as VITEK®, Phoenix® or MicroScan®)	Phenotypic determination: biochemical characterization	Isolate
		40127 - Orientation tests prior to identification of a micro-organism	Phenotypic determination: biochemical characterization	Isolate
		40130 - Gram staining (on colony)	Microscopic examination including preparation	Isolate
		40140 - Kirby Bauer (per bacterium) (diffusion antibiogram)	Phenotypic determination: sensitivity tests	Isolate
		40164 - Cerebrospinal fluid (CSF) (culture)	Bacterial culture	CSF
		40165 - Biological fluid (other than CSF) (culture)	Bacterial culture	Other biological fluids
		40200 - Neisseria gonorrhoeae (culture) (all sites)	Bacterial culture	Clinical sample, secretions
		40201- Staphylococcus aureus (nose) (culture) (except MRSA)	Bacterial culture	Clinical sample
		40242 - Deep pus (with search for anaerobes, including actinomycess)	Bacterial culture	Clinical sample, other biological fluids
		40243 - Superficial pus (without anaerobes)	Bacterial culture	Clinical sample, other biological fluids
		40260 - Conjunctival secretions (culture)	Bacterial culture	Clinical sample, secretions
		40261 - Tracheobronchial secretions (culture)	Bacterial culture	Clinical sample, secretions
		40262- Vaginal secretions	Bacterial culture	
		(culture, fresh, KOH)	Microscopic examination including preparation	Secretions
		40263 - Feces (culture)	Bacterial culture	Feces





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		40266 - Methicillin-resistant Staphylococcus aureus (MRSA) (specific culture) (chromogenic agar screening)	Bacterial culture	Clinical sample, secretions
		40280 - Vaginal secretions (Gram direct for vaginosis)	Microscopic examination including preparation	Secretions
		40310 - Urine (all sampling methods)	Bacterial culture	Urine
		40352 - Clostridium difficile (GDH) + (toxins A and B) (ELISA membrane) (rapid test) (stool)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Feces
	07 2 Misrobiology	40740 - Mononucleosis heterophilic antibody (agglutination)	Qualitative or quantitative agglutination	Blood and derived products
	07.2 Microbiology – immunoserology	40812 - Group A streptococcal anti-streptolysin O (ASO) IgG or total antibodies (quantitative) (manual)	Qualitative or quantitative agglutination	Blood and derived products
	07.3 Microbiology – mycobacteriology	40900 - Mycobacteria (blood culture)	Mycobacterial culture	Blood and derived products
	07.4 Microbiology – mycology	41071 - Deep mycosis (including yeasts)	Fungal culture	Clinical sample, other biological fluids
	07.5 Microbiology – parasitology	41120 - Malaria (rapid Ag detection) (immunochromatography)	Immunochromatography	Blood and derived products
	08.1 Pathology – clinical	60050 - Special staining	Microscopic examination including preparation	Tissue/cell blocks (paraffin, others)
08.0 ANATOMICAL PATHOLOGY		60200 - Routine staining, paraffin-embedded tissue	Microscopic examination including preparation	Tissue/cell blocks (paraffin, others)
PATHOLOGY		60141 - Extemporaneous examination (including staining)	Microscopic examination including preparation	Fresh tissue

<u>Notes</u>

ISO 15189:2012: Medical laboratories — Requirements for quality and competence

ISO 22870:2016: Point-of-care testing (POCT) — Requirements for quality and competence

CAN/CSA-Z902-20 - Blood and Blood Components

POV-ASB: Accreditation Program Overview





This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC). The original version is available in the Directory of Accredited Laboratories on the SCC website at www.scc.ca.

Elias Rafoul Vice President, Accreditation Services Publication on: 2023-11-17