

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 Hôpital Santa Cabrini)
Contact name:	Bruno Lamontagne, Clinico-administrative Director, Direction of the OPTILAB Montréal-CHUM cluster
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SCC File Number:	151129
Provider:	BNQ-EL
Provider File Number:	56658-1
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 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)
- Institut de cardiologie de Montréal, 5000, Bélanger St., Montréal (Québec) H1T 1C8 (CCN no.: 151138 / BNQ no. : 56667-1)

SCOPE OF ACCREDITATION

01.0 BIOCHEMISTRY*

- 01.1 BIOCHEMISTRY – CLINICAL
- 01.2 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

SCOPE OF ACCREDITATION

07.0 MICROBIOLOGY

- 07.1 MICROBIOLOGY – BACTERIOLOGY
- 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)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30009 - Folic acid (folates)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30013 - Uric Acid	Spectrophotometry	Blood and derived products, urine
		30016 - Alanine aminotransferase (ALT)	Spectrophotometry	Blood and derived products
		30017 - Albumin	Spectrophotometry	Blood and derived products
		30022 - Alpha-fetoprotein (AFP)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30029 - Ammoniac	Spectrophotometry	Blood and derived products
		30030 - Total amylase	Spectrophotometry	Blood and derived products
		30038 - Carcinoembryonic antigen (CEA)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30039 - Prostate-specific antigen (PSA) test	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	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
		30079 - Urine (microscopic examination) (automated)	Flow cytometry	Urine
		30083 - Bilirubin Direct (conjugated)	Spectrophotometry	Blood and derived products

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30084 - Bilirubin total	Spectrophotometry	Blood and derived products
		30100 - CA 125	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30105 - Calcium total	Electrochemistry	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
		30124 - Total CO2 or bicarbonate (dosage only)	Electrochemistry	Blood and derived products
		30130 - CK total	Spectrophotometry	Blood and derived products
		30132 - Creatinine	Spectrophotometry	Blood and derived products, urine
		30133 - Cristaux (synovial fluid)	Microscopic examination including preparation	Other biological fluids
		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 (pO ₂ , pCO ₂ , pH, HCO ₃ , COHb, metHb, oxyHb, SulfHb, CO ₂ total)	Electrochemistry	Blood and derived products
		30214 - Glucose	Electrochemistry	Blood and derived products, urine
		30248 - Glycated hemoglobin (HbA1c)	Chromatography	Blood and derived products
		30268 - Serum protein immunofixation	Electrophoresis	Blood and derived products
		30273 - Immunoglobulin IgA	Immunoassay - turbidimetry	Blood and derived products
		30277 - Immunoglobulin IgG	Immunoassay - turbidimetry	Blood and derived products
		30279 - Immunoglobulin IgM	Immunoassay - turbidimetry	Blood and derived products
		30301 - Lactate Dehydrogenase (LD)	Spectrophotometry	Blood and derived products
		30306 - Triglyceride lipase	Spectrophotometry	Blood and derived products
		30332 - Total magnesium	Spectrophotometry	Blood and derived products, urine
		30337 - Microalbumin (urine)	Immunoassay - turbidimetry	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

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30391 - Phosphate	Spectrophotometry	Blood and derived products, urine
		30398 - Potassium	Electrochemistry	Blood, urine
		30404 - Total protein (other fluids)	Spectrophotometry	Urine
		30405 - Total protein (blood)	Spectrophotometry	Blood and derived products
		30412 - C-reactive Protein (CRP) (including ultrasensitive)	Immunoassay - turbidimetry	Blood and derived products
		30471 - Occult Blood Stool (qualitative)	Visual reading	Feces
		30478 - Sodium	Electrochemistry	Blood and derived products, urine
		30511 - Transferrin	Immunoassay - turbidimetry	Blood and derived products
		30512 - Triglycerides	Spectrophotometry	Blood and derived products
		30513 - Troponine 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 - Vitamine B12	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	01.2 Biochemistry – hormonal	30128 - Serum or urine cortisol without extraction	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products, urine
		30240 - Follicle-stimulating hormone (FSH)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30241 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (qualitative)	Immunochemistry	Blood and derived products, urine
		30242 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (quantitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30243 - Luteinizing Hormone (LH)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30402 - Prolactin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30500 - T3 total (total triiodothyronine) or free	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30502 - T4L (free thyroxine)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30516 - TSH (thyrotropic hormone)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	01.4 Biochemistry – medication	30600 - Acetaminophen	Immunoassay - turbidimetry	Blood and derived products
		30601 - Valproic acid	Immunoassay - turbidimetry	Blood and derived products
		30630 - Carbamazepine	Immunoassay - turbidimetry	Blood and derived products
		30640 - Digoxine	Immunoassay - turbidimetry	Blood and derived products
		30692 - Lithium (Li)	Spectrophotometry	Blood and derived products
		30731 - Phenytoin	Immunoassay - turbidimetry	Blood and derived products
		30760 - Salicylates	Spectrophotometry	Blood and derived products
		30780 - Vancomycine	Immunoassay - turbidimetry	Blood and derived products
	01.5 Biochemistry – toxicology	30851 - Street drugs / strip / drug	Immunochemistry	Urine
	POCT	Transcutaneous assessment of bilirubin levels	NA	Blood and derived products, secretions, urine
		SARS-CoV-2 screening		
		Capillary hemoglobin assay		
		Capillary glucose determination		
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45026 - Clostridioides difficile; detection of toxin B gene (NAAT) on clinical specimen	Detection of nucleic acids	Feces
		45033 - Coronavirus (SARS-CoV-2); detection (NAAT) (rapid test, certified kit) on clinical samples	Detection of nucleic acids	Clinical sample, secretions
		45048 - influenza A and B (NAAT) (certified kit) on clinical specimen	Detection of nucleic acids	Clinical sample
		45053 - Coronavirus (SARS-CoV-2 and Influenza A and B); detection (NAAT) (multiplex) (certified kit) on clinical sample	Detection of nucleic acids	Clinical sample, secretions
05.0 HEMATOLOGY	05.2 Hematology – cytology	20320 - Liquid cytology (manual)	Microscopic examination including preparation	Other biological fluids, CSF
		20321 - Fluid cytology with cytopspin	Microscopic examination including preparation	Other biological fluids, CSF
		20361 - Complete blood count (CBC) or automated Hgb-HCT-Plat.	Impedance measurement	Blood and derived products
			Spectrophotometry	
			Calculation	
		20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	Blood and derived products and bone marrow

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		20363 - Evaluation of red blood cells and platelets (orientation smear) (including staining)	Microscopic examination including preparation	Blood and derived products
		20381 - Automated sedimentation	Precipitation	Blood and derived products
		20470 - Reticulocytes (automated)	Impedance measurement	Blood and derived products
	Flow cytometry			
	05.5 Hematology – hemostasis	20062 - D-Dimer (automated)	Aggregometry	Blood and derived products
			Coagulometry	
			Immunoassay - turbidimetry	
			Spectrophotometry	
		20240 - Activated partial thromboplastin time (APTT) or trombin time (TT) or prothrombin time (PT)	Coagulometry	Blood and derived products
			Immunoassay - turbidimetry	
		20241 - Activated partial thromboplastin time or partial thromboplastin time + activator (APTT)	Coagulometry	Blood and derived products
	Immunoassay - turbidimetry			
	20243 - Prothrombin time (INR) including fibrinogen derivative	Coagulometry	Blood and derived products	
		Immunoassay - turbidimetry		
	05.7 Hematology – immunology	20774 - Cryoglobulins (qualitative)	Precipitation	Blood and derived products
Visual reading				
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10007 - Irregular antibodies (manual identification)	Immunological method of hemagglutination and derivative	Blood and derived products
		10024 - Compatibility (manual or automated)	Immunological method of hemagglutination and derivative	Blood and derived products
		10028 - Coombs direct polyspecific or monospecific (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
		10034 - Polyspecific or monospecific direct coombs (gel 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
		10085 - ABO-Rh blood group (automated)	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

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		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
		10150 - Irregular antibodies (manual search)	Immunological method of hemagglutination and derivative	Blood and derived products
		10153 - Irregular antibodies (automated search)	Immunological method of hemagglutination and derivative	Blood and derived products
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	40020 - Multi-resistant gram-negative bacteria (bêta-lactamase-ESBL, carbapenemase) (screening)	Bacterial culture	Feces
		40026 - Bronchoscopy (semi-quantitative culture)	Bacterial culture	Clinical sample, secretions
		40047 - Minimum inhibitory concentration (MIC) microplate/automated card (per bacterium)	Phenotypic determination: sensitivity tests	Isolate
		40048 - Minimum inhibitory concentration (MIC) (strip) (per antibiotic)	Phenotypic determination: sensitivity tests	Clinical sample
		40049 - Semi-quantitative culture from a primary specimen (catheter)	Bacterial culture	Clinical sample
		40063 - Vancomycin-resistant Enterococcus (VRE) (specific culture) (chromogenic agar screening)	Bacterial culture	Clinical sample, feces
			Chromogenic method	
		40065 - Expectorations (bacteriology) (includes specimen rejected after Gram)	Microscopic examination including preparation	Clinical sample, secretions
			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)	Phenotypic determination: biochemical characterization	Isolate
		40127 - All orientation tests prior to identification of a micro-organism	Phenotypic determination: biochemical characterization	Isolate
		40130 - Gram staining (on colony)	Microscopic examination including preparation	Other biological fluids, CSF, Isolate, secretions, blood and derived products, clinical samples
		40140 - Kirby Bauer (per bacterium) (diffusion antibiogram)	Phenotypic determination: sensitivity tests	Isolate

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		40160 - Legionella (urinary antigen)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Urine
		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, secretions
		40220 - Ear or external auditory canal (culture)	Bacterial culture	Clinical sample, secretions
		40242 - Deep pus (with search for anaerobes, including actinomycess)	Bacterial culture	Clinical sample or other biological fluids
		40243 - Superficial pus (without anaerobes, including Actinomyces)	Bacterial culture	Clinical sample
		40260 - Conjunctival secretions (culture)	Bacterial culture	Clinical sample, secretions
		40262- Vaginal secretions (culture, fresh, KOH)	Microscopic examination including preparation	Secretions
		40263 - Feces (culture)	Bacterial culture	Feces
		40266 - Methicillin-resistant Staphylococcus aureus (MRSA) (specific culture) (chromogenic agar screening)	Bacterial culture Chromogenic method	Clinical sample, secretions
		40280 - Vaginal secretions (Gram direct for vaginosis)	Microscopic examination including preparation	Secretions
		40310 - Urine (all sampling methods)	Bacterial culture	Urine
		07.2 Microbiology – immunoserology	40740 - Mononucleosis heterophilic antibody (agglutination)	Qualitative or quantitative agglutination
	40840 - HIV IgG or total Ac (rapid test)		Immunoblotting	Blood and derived products
	07.3 Microbiology – mycobacteriology	40900 - Mycobacteria (blood culture)	Microscopic examination including preparation	Blood and derived products
			Mycobacterial culture	
		40902 - Mycobacteria (solid and liquid culture)	Microscopic examination including preparation	Clinical sample
			Mycobacterial culture	
	40904 - Mycobacteria (direct examination on clinical specimen) (auramine)	Microscopic examination including preparation	Clinical sample	
	40907 - Mycobacteria (direct examination on clinical specimen) (Ziehl)	Microscopic examination including preparation	Clinical sample	
	07.4 Microbiology – mycology	41031- Mycoses (blood culture)	Microscopic examination including preparation	Blood and derived products

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
			Fungal culture	
		41050 - Yeast (specific culture)	Microscopic examination including preparation Fungal culture	Clinical sample
		41051 - Multi-resistant yeast (Candida auris) (screening)	Fungal culture Chromogenic method	Clinical sample
		41073 - Minimum inhibitory concentration (MIC) (automated microplate) by yeast	Phenotypic determination: sensitivity tests	Isolate
	07.5 Microbiology – parasitology	41120 - Malaria (rapid Ag detection) (immunochromatography)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		41140 - Oxyures (search for) (by tape)	Microscopic examination including preparation	Clinical sample, feces
		41171 - Trichomonas vaginalis (ag detection)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Secretions
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60050 - Special staining	Microscopic examination including preparation	Tissue/cell blocks (paraffin, others), fresh tissue
		60141 - Extemporaneous examination (including staining)	Microscopic examination including preparation	Fresh tissue
		60200 - Routine staining, paraffin-embedded tissue	Microscopic examination including preparation	Tissue/cell blocks (paraffin, others)

Notes

Accreditation is granted under a flexible scope. The list of methods subject to accreditation is available.

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.

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