

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 Jean-Talon)
Contact name:	Bruno Lamontagne, Clinico-administrative Director, Direction of the OPTILAB Montréal- CHUM cluster
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SCC File Number:	151136
Provider:	BNQ-EL
Provider File Number:	56665-1
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)

- 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 – C	CLINICAL
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- 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

07.0 MICROBIOLOGY

07.1 MICROBIOLOGY – BACTERIOLOGY



SCOPE OF ACCREDITATION

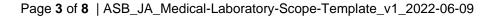
- 07.2 MICROBIOLOGY IMMUNOSEROLOGY
- 07.4 MICROBIOLOGY MYCOLOGY
- 07.5 MICROBIOLOGY PARASITOLOGY

08.0 ANATOMICAL PATHOLOGY

- 08.1 PATHOLOGY CLINICAL
- 08.3 PATHOLOGY CYTOLOGY

DETAILS OF SCOPE OF ACCREDITATION

Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30005 - Beta-hydroxybutyrate (whole blood)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30010 - Lactic acid (colorimetric)	Spectrophotometry	Blood and derived products, CSF
		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)	Enzymatic method	Blood and derived products
		30017 - Albumin	Spectrophotometry	Blood and derived products, other biological fluids
	01.1 Biochemistry –	30029 - Ammoniac	Enzymatic method	Blood and derived products
01.0 BIOCHEMISTRY	clinical	30030 - Total amylase	Enzymatic method	Blood and derived products, other biological fluids
		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)	Enzymatic method	Blood and derived products	
		30083 - Bilirubin Direct (conjugated)	Spectrophotometry	Blood and derived products
		30084 - Bilirubin total	Spectrophotometry	Blood and derived products
		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	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	Enzymatic method	Blood and derived products
		30119 - Cholesterol total	Enzymatic method	Blood and derived products
		30124 - Total CO2 or bicarbonate (dosage only)	Spectrophotometry	Blood and derived products
		30124 - Total CO2 or bicarbonate (dosage only)	Calculation	Blood and derived products
		30130 - CK total	Enzymatic method	Blood and derived products
		30132 - Creatinine	Spectrophotometry	Blood and derived products, urine, other biological fluids
		30190 - Iron (binding capacity) (UIBC or TIBC)	Calculation	Blood and derived products
		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)	Enzymatic method	Blood and derived products
		30212 - Blood Gas (pO2, pCO2, pH,	Electrochemistry	Discological deviced are ducto
		HCO3, COHb, metHb, oxyHb, SulfHb)	Co-oximetry	Blood and derived products
		30214 - Glucose	Enzymatic method	Blood and derived products, urine, CSF, other biological fluids
		30301 - Lactate Dehydrogenase (LD)	Enzymatic method	Blood and derived products, other biological fluids
		30306 - Triglyceride lipase	Enzymatic method	Blood and derived products, other biological fluids
		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	Enzymatic method	Blood and derived products
		30391 - Phosphate	Spectrophotometry	Blood and derived products, urine
		30398 - Potassium	Electrochemistry	Blood and derived products, urine





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30399 - Prealbumin	Immunoassay - turbidimetry	Blood and derived products
		30404 - Total protein (other fluids)	Spectrophotometry	CSF, urine, other biological fluids
		30405 - Total protein (serum)	Spectrophotometry	Blood and derived products
		30412 - C-reactive Protein (CRP) (including ultrasensitive)	Immunoassay - turbidimetry	Blood and derived products
		30478 - Sodium	Electrochemistry	Blood and derived products, urine
		30511 - Transferrin	Immunoassay - turbidimetry	Blood and derived products
		30512 - Triglycerides	Enzymatic method	Blood and derived products, other biological fluids
		30513 - Troponin T or I	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30531 - Urea	Enzymatic method	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 – hormonal	30241 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (qualitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products, urine
		30242 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (quantitative)	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
		30600 - Acetaminophen	Immunoassay - turbidimetry	Blood and derived products
	01.4 Biochemistry – medication	30601 - Valproic acid	Immunoassay - turbidimetry	Blood and derived products
		30630 - Carbamazepine	Immunoassay - turbidimetry	Blood and derived products
		30640 - Digoxin	Immunoassay - turbidimetry	Blood and derived products
		30692 - Lithium (Li)	Spectrophotometry	Blood and derived products
		30731 - Phenytoin	Immunoassay - turbidimetry	Blood and derived products
		30760 - Salicylates	Enzymatic method	Blood and derived products
		30780 - Vancomycin	Immunoassay - turbidimetry	Blood and derived products





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30177 - Ethanol (ethyl alcohol)	Enzymatic method	Blood and derived products
	01.5 Biochemistry – toxicology	30851 - Street drugs / strip / drug	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Urine
		Capillary glucose determination		
		Summary examination (urine) (visual reading)		
		Blood gas analysis with or without co- oximetry (pO2, pCO2, pH, HCO3, COHb, meHb, oxyHb, SulfHb, total CO2)		
		Diagnostic test panel (Multiparametric)		
		Determination of activated partial thromboplastin time (ACT) (coagulometer)		Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
		Tear pH measurement		
	РОСТ	Hemoglobin determination	NA	
		Amniotic membrane rupture test		
		Transcutaneous assessment of bilirubin levels		
		Detection of occult blood in stool		
		Vaginal secretions analysis		
		White blood cell count and neutrophil percentage		
		Group A streptococcus detection		
		Chorionic gonadotropin hormone detection		
		45031 - Coronavirus (SARS-CoV-2); detection (NAAT) (certified kit) on clinical specimen	Detection of nucleic acids	Secretions
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45131 - Respiratory viruses; multiplex detection of 3 viruses (influenza A, influenza B and RSV) (NAAT) (multiplex) (certified kit) on clinical specimen	Detection of nucleic acids	Secretions
	05.2 Hematology – cytology	20321 - Fluid cytology with cytospin	Microscopic examination including preparation	CSF, other biological fluids
		20361 - Complete blood count (CBC) or automated Hgb-HCT-Plat.	Flow cytometry	Blood and derived products
05.0 HEMATOLOGY			Calculation	Blood and derived products
			Impedance measurement	Blood and derived products
		20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	Blood and derived products





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
		20470 - Reticulocytes (automated)	Impedance measurement	Blood and derived products
			Flow cytometry	Blood and derived products
		20490 - Manual sedimentation	Precipitation	Blood and derived products
			Visual reading	Blood and derived products
		20044 - Cryofibrinogen	Precipitation	Blood and derived products
			Visual reading	Blood and derived products
		20062 - D-Dimer (automated)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	05.5 Hematology – hemostasis	20240 - Activated partial thromboplastin time (APTT) or thrombin time (TT) or prothrombin time (PT) (INR) on 50/50 mixture	Photometry	Blood and derived products
		20241 - Activated partial thromboplastin time or partial thromboplastin time + activator (APTT)	Photometry	Blood and derived products
		20243 - Prothrombin time (INR) including fibrinogen derivative	Photometry	Blood and derived products
	05.7 Hematology – immunology	20774 - Cryoglobulins (qualitative)	Precipitation	Blood and derived products
		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
		10032 - Multispecific or monospecific direct coombs (tube technique) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	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	





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
	07.1 Microbiology – bacteriology	40102 - Blood culture (2 bottles: aerobic + anaerobic)	Bacterial culture	Blood and derived products, other biological fluids
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	40740 - Mononucleosis heterophilic antibody (agglutination)	Qualitative or quantitative agglutination	Blood and derived products
	07.5 Microbiology – parasitology	41120 - Malaria (rapid Ag detection) (immunochromatography)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		60050 - Special staining	Microscopic examination including preparation	Tissue/cell blocks (paraffin, others), cells and fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60141 - Extemporaneous examination (including staining)	Microscopic examination including preparation	Clinical sample, other biological fluids, fresh tissue
		60200 - Routine staining, paraffin- embedded tissue	Microscopic examination including preparation	Tissue/cell blocks (paraffin, others), cells and 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 <u>www.scc.ca</u>.

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

