

## 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 Notre-Dame**)

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SCC File Number:	151133
Provider:	BNQ-EL
Provider File Number:	56662-1
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 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
 07.5 MICROBIOLOGY – PARASITOLOGY

# **DETAILS OF SCOPE OF ACCREDITATION**

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		30005 - Beta-hydroxybutyrate (whole blood)	Electrochemistry	Blood and derived products
		30010 - Lactic acid (colorimetric)	Spectrophotometry	Blood and derived products, other biological fluids, CSF
			30013 - Uric Acid	Spectrophotometry
		30016 - Alanine aminotransferase (ALT)	Spectrophotometry	Blood and derived products
		30017 - Albumin	Spectrophotometry	Blood and derived products, other biological fluids
		30029 - Ammoniac	Spectrophotometry	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
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	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
		30105 - Calcium total	Electrochemistry	Blood and derived products, urine
		30106 - Calcium Ionized	Electrochemistry	Blood and derived products
		30115 - Chloride	Electrochemistry	Blood and derived products, other biological fluids, CSF, feces, urine
		30116 - Cholesterol – HDL	Spectrophotometry	Blood and derived products
		30119 - Cholesterol total	Spectrophotometry	Blood and derived products, other biological fluids
		30124 - Total CO2 or bicarbonate (dosage only)	Electrochemistry	Blood and derived products
		30130 - CK total	Spectrophotometry	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		30132 - Creatinine	Spectrophotometry	Blood and derived products, urine, other biological fluids
		30133 - Crystals (synovial fluid)	Microscopic examination including preparation	Other biological fluids
		30191 - Iron (serum)	Spectrophotometry	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, CO2	Co-oximetry	Blood and derived products
		total)	Calculation	
		30214 - Glucose	Spectrophotometry	Blood and derived products, other biological fluids, CSF, urine
			Electrochemistry	Blood and derived products
		30301 - Lactate Dehydrogenase (LD)	Spectrophotometry	Blood and derived products, CSF, other biological fluids
		30306 - Triglyceride lipase	Spectrophotometry	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, feces, other biological fluids
		30383 - pH (biological fluid)	Electrochemistry	Other biological fluids
		30386 - Alkaline Phosphatase	Spectrophotometry	Blood and derived products, other biological fluids
		30391 - Phosphate	Spectrophotometry	Blood and derived products, urine, feces
		30398 - Potassium	Electrochemistry	Blood and derived products, urine, feces
		30404 - Total protein (other fluids)	Spectrophotometry	Other biological fluids, urine, CSF
		30405 - Total protein (serum)	Spectrophotometry	Blood and derived products, other biological fluids
		30412 - C-reactive Protein (CRP) (including ultrasensitive)	Immunoassay - turbidimetry	Blood and derived products
		30471 - Occult Blood Stool (qualitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Feces
		30478 - Sodium	Electrochemistry	Blood and derived products, urine, feces
		30511 - Transferrin	Immunoassay - turbidimetry	Blood and derived products
		30512 - Triglycerides	Spectrophotometry	Blood and derived products, other biological fluids
		30513 - Troponine T or I	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30531 - Urea	Electrochemistry	Blood and derived products, urine





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		30532 - Urine (microscopic exam)	Microscopic examination including preparation	Urine
		30533 - Urine (summary examination)	Reflectance	Urine
			Refractometry	
		30241 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (qualitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Urine
	01.2 Biochemistry – hormonal	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
		30601 - Valproic acid	Immunoassay - turbidimetry	Blood and derived products
		30630 - Carbamazepine	#N/A	Blood and derived products
	01.4 Biochemistry –	30640 - Digoxine	Immunoassay - turbidimetry	Blood and derived products
	medication	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
		30177 - Ethanol (ethyl alcohol)	Spectrophotometry	Blood and derived products, urine
		30604 - Amphetamines/methamphet amine (other than strip) (automated)	Spectrophotometry	Urine
		30621 - Benzodiazepines (other than strip) (automated)	Spectrophotometry	Urine
	01.5 Biochemistry – toxicology	30701 - Methadone (other than strip) (automated)	Spectrophotometry	Urine
		30831 - Cannabinoids (THC) (other than strip) (automated)	Spectrophotometry	Urine
		30834 - Cocaine (other than strip) (automated)	Spectrophotometry	Urine
		30890 - Opiates (other than screening) (automated)	Spectrophotometry	Urine
		30891 - PCP (other than screening) (automated)	Spectrophotometry	Urine
	РОСТ	Capillary glucose determination Hemoglobin determination	NA	Blood and derived products, urine, secretions, clinical sample, other biological fluids





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		Summary examination (urine) (manual reading)		
		Summary examination (urine) (automated reading)		
		Detection of chorionic gonadotropin hormone (HCG)		
		Tear pH measurement		
		Vaginal secretions analysis		
		Street drug detection		
		Leukocyte count and neutrophil percentage		
		Group A streptococcus detection		
		45026 - Clostridium difficile; detection of toxin B gene (NAAT) on clinical specimen	Detection of nucleic acids	Feces
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45033 - Coronavirus (SARS- CoV-2); detection (NAAT) (rapid test, certified kit) on clinical samples	Detection of nucleic acids	Secretion, clinical sample
		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	Clinical sample
		20320 - Liquid cytology (manual)	Microscopic examination including preparation	Other biological fluids
	05.2 Hematology – cytology  05.5 Hematology – hemostasis	20361 - Complete blood count (CBC) or automated Hgb-HCT-Plat.	Flow cytometry	
			Impedance measurement	Blood and derived products, other biological fluids
			Spectrophotometry	
			Calculation	
		20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	Blood and derived products
05.0 HEMATOLOGY		20364 - Complete blood count (CBC) or Hb-Ht-Plaq. Micro-method (automated)	Flow cytometry	
			Impedance measurement	Blood and derived products
			Calculation	
			Spectrophotometry	
		20470 - Reticulocytes (automated)	Flow cytometry	Blood and derived products
		20490 - Manual sedimentation	#N/A	Blood and derived products
		20044 - Cryofibrinogen	Precipitation	Blood and derived products
			Visual reading	biood and derived products
		20062 - D-Dimer (automated)	Chronometric method	Blood and derived products
		20102 - Fibrinogen (activity)	Chronometric method	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		20240 - Activated partial thromboplastin time (APTT) or thrombin time (TT) or prothrombin time (PT) (INR) on 50/50 mixture	Chronometric method	Blood and derived products
	20241 - Activated partial thromboplastin time or partial thromboplastin time + activator (APTT)	Chronometric method	Blood and derived products	
		20243 - Prothrombin time (INR) including fibrinogen derivative	Chronometric method	Blood and derived products
		20245 - In vitro bleeding time (per agent) (PFA-100)	Aggregometry	Blood and derived products
		20248 - Thrombin time (TT)	Chronometric method	Blood and derived products
	05.7 Hematology –	20774 - Cryoglobulins	Precipitation	Blood and derived products
	immunology	(qualitative)	Visual reading	
	06.0 Transfusion medicine	10000 - Cold agglutinins (screening) (qualitative) including autocontrols	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
		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
06.0 TRANSFUSION MEDICINE		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
		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
		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





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
	07.1 Microbiology – bacteriology	40101 - Blood culture (1 bottle: aerobic or anaerobic)	Bacterial culture	Blood and derived products
		40102 - Blood culture (2 bottles: aerobic + anaerobic)	Bacterial culture	Blood and derived products
07.0 MICROBIOLOGY		40130 - Gram staining (on colony)	Microscopic examination including preparation	Blood and derived products
	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
		41122 - Malaria (reading and identification, including % parasitaemia)	Microscopic examination including preparation	Blood and derived products

# **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 <a href="https://www.scc.ca">www.scc.ca</a>.

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