

# 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 Fleury**)

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SCC File Number:	151135
Provider:	BNQ-EL
Provider File Number:	56664-1
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 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 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



# **SCOPE OF ACCREDITATION**

### 06.0 TRANSFUSION MEDICINE

### 07.0 MICROBIOLOGY

07.1 MICROBIOLOGY – BACTERIOLOGY
 07.2 MICROBIOLOGY – IMMUNOSEROLOGY
 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)
		30010 - Lactic acid (colorimetric)	Enzymatic method	Blood and derived products
		30009 - Folic acid (folates)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	
		30013 - Uric Acid	Spectrophotometry	Blood and derived products, urine, other biological fluids
		30016 - Alanine aminotransferase (ALT)	Enzymatic method	Blood and derived products
		30017 - Albumin	Spectrophotometry	Blood and derived products, other biological fluids, urine
		30029 - Ammoniac	Enzymatic method	Blood and derived products
		30030 - Total amylase	Enzymatic method	Blood and derived products, other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30039 - Prostate-specific antigen (PSA) test	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	
		30060 - Aspartate aminotransferase (AST)	Enzymatic method	Blood and derived products
		30083 - Bilirubin Direct (conjugated)	Spectrophotometry	
		30084 - Bilirubin total		
		30095 - NT-PRO-BNP (Brain Natriuretic Peptide)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	
		30105 - Calcium total		Blood and derived products, urine, other biological fluids
		30106 - Calcium Ionized	Electrochemistry	Blood and derived products
		30115 - Chloride		Blood and derived products, urine, other biological fluids





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		30116 - Cholesterol – HDL		Blood and derived products
		30119 - Cholesterol total	Enzymatic method	Blood and derived products, other biological fluids
		30130 - CK total		Blood and derived products
		30132 - Creatinine	Spectrophotometry	Blood and derived products, urine, other biological fluids
		30133 - Crystals (synovial fluid)	Microscopic examination including preparation	Other biological fluids
		30190 - Iron (binding capacity) (UIBC or TIBC)	Calculation	
		30191 - Iron (serum)	Spectrophotometry	
		30193 - Ferritin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		30210 - Gamma glutamyl transferase (GGT)	Enzymatic method	·
		30212 - Blood Gas (pO2, pCO2, pH, HCO3, COHb,	Co-oximetry	
		metHb, oxyHb, SulfHb, CO2 total)	Electrochemistry	
		30214 - Glucose		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		
		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, other biological fluids
		30391 - Phosphate	Spectrophotometry	Blood and derived products, urine
		30398 - Potassium	Electrochemistry	Blood and derived products, urine, other biological fluids
		30404 - Total protein (other fluids)	Spectrophotometry	Urine, CSF and other biological fluids
		30405 - Total protein (serum)		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, other biological fluids
		30511 - Transferrin	Immunoassay - turbidimetry	Blood and derived products
		30512 - Triglycerides	Enzymatic method	Blood and derived products, other biological fluids





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		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	onne
		30553 - Vitamin B12		Blood and derived products
		30241 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (qualitative)		Blood and derived products, urine
		30242 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (quantitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	
		30500 - T3 total (total triiodothyronine) or free		
	01 2 Biochomistry	30502 - T4L (free thyroxine)		
	01.2 Biochemistry – hormonal	30516 - TSH (thyrotropic hormone)		Blood and derived products
		30600 - Acetaminophen	Immunoassay - turbidimetry	Blood and derived products
		30640 - Digoxine	Immunoassay - turbidimetry	
		30692 - Lithium (Li)	Spectrophotometry	
		30760 - Salicylates		
	01 F Biochomistry	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)		Blood and derived products,
	РОСТ	Diagnostic test panel (Multiparametric)	NA -	urine, feces, secretions, clinical sample, other biological fluids
		Determination of activated partial thromboplastin time (ACT) (coagulometer)		
		Tear pH measurement		
		Hemoglobin determination		
		Amniotic membrane rupture test		





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		Transcutaneous assessment of bilirubin levels		
		Detection of occult blood in stool		
		Vaginal secretions analysis		
		White blood cell count and neutrophil percentage		
		SARS-CoV-2 screening		
		Group A streptococcus detection		
		RH factor determination (Rhesus on slide)		
		Chorionic gonadotropin hormone detection		
	02.3 Molecular diagnosis – infectious diseases	45031 - Coronavirus (SARS- CoV-2); detection (NAAT) (certified kit) on clinical specimen		Secretion, clinical sample
02.0 MOLECULAR BIOLOGY		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	
	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.	Calculation	Blood and derived products, other biological fluids
			Impedance measurement	
			Flow cytometry	
		20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	
		20363 - Evaluation of red blood cells and platelets (orientation smear) (including staining)	Microscopic examination including preparation	
		20364 - Complete blood count (CBC) or Hb-Ht-Plaq. Micro- method (automated)	Flow cytometry	
05.0 HEMATOLOGY			Impedance measurement	
		20490 - Manual sedimentation	Precipitation	Blood and derived products
		20450 - Platelets (blood) (manual)	Visual reading	
		20470 - Reticulocytes (automated)	Impedance measurement	
		20470 - Reticulocytes (automated)	Flow cytometry	
	05.5 Hematology – hemostasis	20044 - Cryofibrinogen	Precipitation	
		20044 - Cryofibrinogen	Visual reading	
		20061 - D-Dimer (ELISA)	Immunoassay - turbidimetry	





Discipline	Sub-discipline	Analytical parameter	Analytical principle	Matrix (sample)
		20240 - Activated partial thromboplastin time (APTT) or thrombin time (TT) or prothrombin time (PT) (INR) on 50/50 mixture		
		20241 - Activated partial thromboplastin time or partial thromboplastin time + activator (APTT)	Photometry	
		20243 - Prothrombin time (INR) including fibrinogen derivative		
	05.7 Hematology –	20774 - Cryoglobulins (qualitative)	Precipitation	
	immunology	20774 - Cryoglobulins (qualitative)	Visual reading	
		10007 - Irregular antibodies (manual identification)		
		or automated)		
	06.0 Transfusion medicine	10032 - Multispecific or monospecific direct coombs (tube technique) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products, cells
06.0 TRANSFUSION MEDICINE		10086 - ABO-Rh blood type (manual)		Blood and derived products
		10136 - Common erythrocyte phenotype (patient or product / by antigen / excluding ABO, D / including controls) (manual)		Blood and derived products, cells
		10150 - Irregular antibodies (manual search)		Blood and derived products
07.0 MICROBIOLOGY	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)	
07.0 MICROBIOLOGY		41121 - Malaria (smear + thick drop) (preparation and staining)	Microscopic examination including preparation	Blood and derived products
		41122 - Malaria (reading and identification, including % parasitaemia)		
08.0 ANATOMICAL PATHOLOGY	.OGY 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		Tissue/cell blocks (paraffin, others), cells, fresh tissue





# **Notes**

**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