

# **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 du Sacré-Cœur de Montréal)		
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SCC File Number:	151134
Provider:	BNQ-EL
Provider File Number:	56663-1
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:	2024-08-18
Accreditation Valid to:	2029-03-25

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 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
- 01.3 BIOCHEMISTRY IMMUNOLOGY
- 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

- 05.1 HEMATOLOGY CYTOCHEMISTRY
- 05.2 HEMATOLOGY CYTOLOGY
- 05.3 HEMATOLOGY ERYTHROCYTIC
- 05.4 HEMATOLOGY GRAFTS
- 05.5 HEMATOLOGY HEMOSTASIS





# **SCOPE OF ACCREDITATION**

05.7 HEMATOLOGY – IMMUNOLOGY

## 06.0 TRANSFUSION MEDICINE

# 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
- 08.3 PATHOLOGY CYTOLOGY

# DETAILS OF SCOPE OF ACCREDITATION

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Physical characterization	Reflectance	Urine and secretions
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Physical characterization	Refractometry	Urine, other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Osmolality measurement	Cryoscopic Osmometry	Blood and derived products, feces, urine, other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Calculation	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Spectrophotometry	Blood and derived products, feces, urine and other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Chromatography	Blood and blood products, feces, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Co-oximetry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of	Electrophoresis	CSF, blood and derived products, urine





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		organic and inorganic molecules and enzyme activity		
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Microscopic examination including preparation	Blood and derived products, urine, other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	CSF, blood and derived products, other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Immunoassay - turbidimetry	Blood and blood products, feces, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Enzymatic method	Blood and derived products, urine, CSF, other biological fluids
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Electrochemistry	Blood and derived products, other biological fluids, feces
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Precipitation	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Visual reading	Blood and derived products
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Enzyme immunoassays (chemiluminescence, ELISA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Visual reading	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	Research, identification and/or determination of the concentration of xenobiotics/drugs	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Enzyme immunoassays (chemiluminescence, ELISA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Immunoassay - turbidimetry	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.5 Biochemistry – toxicology	Research, identification and/or determination of the concentration of toxic substances or analytes	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.5 Biochemistry – toxicology	Research, identification and/or determination of the concentration of toxic substances or analytes	Spectrophotometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Capillary glucose assay	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Summary examination (urine) (visual reading)	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Blood gas analysis with or without co-oximetry (pO2, pCO2, pH, HCO3, COHb, meHb, oxyHb, SulfHb, total CO2)	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Diagnostic test panel (Multiparametric)	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Determination of activated partial thromboplastin time (ACT) (coagulometer)	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Tear pH measurement	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Hemoglobin determination	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Amniotic membrane rupture test	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Transcutaneous assessment of bilirubin levels	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Analysis of vaginal secretions	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	White blood cell count and neutrophil percentage	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	SARS-CoV-2 screening	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of	Detection of group A streptococcus	Blood and derived products, urine, feces, secretions,







Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		organic and inorganic molecules and enzyme activity		clinical sample, other biological fluids
01.0 BIOCHEMISTRY	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Detection of chorionic gonadotropin hormone (HCG)	Blood and derived products, urine, feces, secretions, clinical sample, other biological fluids
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	Research and identification and/or determination of the concentration (quantification) of viral, bacterial and fungal nucleic acids	Detection of nucleic acids	CSF, blood and derived products
05.0 HEMATOLOGY	05.1 Hematology – cytochemistry	Determination of hematocytochemistry parameters	Microscopic examination including preparation	Cells, marrow
05.0 HEMATOLOGY	05.1 Hematology – cytochemistry	Hemogram, research, identification and/or cells quantification	Microscopic examination including preparation	Cells, marrow, urine
05.0 HEMATOLOGY	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Calculation	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Flow cytometry	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Microscopic examination including preparation	Marrow, blood and derived products, other biological fluids, CSF
05.0 HEMATOLOGY	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Impedance measurement	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	Red blood cell aggregation technique	Precipitation	Blood and derived products
05.0 HEMATOLOGY	05.3 Hematology – erythrocytic	Physical characterization	Viscometry	Blood and derived products
05.0 HEMATOLOGY	05.3 Hematology – erythrocytic	Search for cellular abnormalities	Microscopic examination including preparation	Blood and derived products
05.0 HEMATOLOGY	05.3 Hematology – erythrocytic	Research and determination of hemoglobin concentration	Electrophoresis	Blood and derived products
05.0 HEMATOLOGY	05.3 Hematology – erythrocytic	Research and determination of hemoglobin concentration	Spectrophotometry	Blood and derived products, other biological fluids, CSF
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Determination of hemostasis parameters	Coagulometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Determination of hemostasis parameters	Spectrophotometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Determination of hemostasis parameters	Chromogenic method	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Determination of hemostasis parameters	Photometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Determination of hemostasis parameters	Turbidimetry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Platelet tests, search for and determination of heparin- dependent antibody concentration	Enzyme immunoassays (chemiluminescence, ELISA and derivatives)	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	Platelet tests, search for and determination of heparin- dependent antibody concentration	Aggregometry	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
05.0 HEMATOLOGY	05.6 Hematology – immunocytometry	Hematocytological phenotyping	Flow cytometry	Blood and derived products, other biological fluids, CSF, marrow
05.0 HEMATOLOGY	05.7 Hematology – immunology	Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Turbidimetry	Blood and derived products
05.0 HEMATOLOGY	05.7 Hematology – immunology	Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Visual reading	Blood and derived products
05.0 HEMATOLOGY	05.7 Hematology – immunology	Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Immunoassay - fluorescence	Blood and derived products
05.0 HEMATOLOGY	05.7 Hematology – immunology	Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	Research and determination of erythrocyte antigens; determination of blood groups	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	Research and/or identification of anti-erythrocytic antibodies	Immunological method of hemagglutination and derivative	Blood and derived products
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Characterization of the sensitivity of bacteria to different substances	Phenotypic determination: sensitivity tests	Clinical sample, isolate
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Preparation for bacterial research and identification	Bacterial culture	Clinical sample, other biological fluids, CSF
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Preparation for bacterial research and identification	Microscopic examination including preparation	Secretions, clinical sample, isolate
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Research and identification of toxins, enzymes, antibodies and bacterial antigens	Phenotypic determination: biochemical characterization	Clinical sample, isolate
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Research and identification of toxins, enzymes, antibodies and bacterial antigens	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Feces, urine, fresh sample, CSF, other biological fluids
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Research and identification of toxins, enzymes, antibodies and bacterial antigens	Immunoassay - fluorescence	Feces, urine, fresh tissue, CSF, other biological fluids
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Research and identification of bacteria	Phenotypic determination by mass spectrometry	Clinical sample
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Research and identification of bacteria	Microscopic examination including preparation	Secretions, clinical sample, isolate
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Qualitative or quantitative agglutination	Blood and derived products
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	Research and identification of mycobacteria	Mycobacterial culture	Clinical sample, blood and derived products, fresh tissue, other biological fluids, CSF





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	Research and identification of mycobacteria	Microscopic examination including preparation	Clinical sample, blood and derived products, fresh tissue, other biological fluids, CSF
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	Research and identification of mycobacteria	Immunoassay - fluorescence	Clinical sample, blood and derived products, fresh tissue, other biological fluids, CSF
07.0 MICROBIOLOGY	07.4 Microbiology – mycology	Research and identification of fungi and yeast	Phenotypic determination: mass spectrometry	Blood and derived products, clinical sample, other biological fluids, CSF
07.0 MICROBIOLOGY	07.4 Microbiology – mycology	Research and identification of fungi and yeast	Fungal culture	Clinical sample, blood and derived products, other biological fluids, CSF
07.0 MICROBIOLOGY	07.4 Microbiology – mycology	Research and identification of fungi and yeast	Microscopic examination including preparation	Clinical sample, blood and derived products, other biological fluids, CSF
07.0 MICROBIOLOGY	07.4 Microbiology – mycology	Research and identification of fungi and yeast	Immunoassay - fluorescence	Clinical sample
07.0 MICROBIOLOGY	07.4 Microbiology – mycology	Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Qualitative or quantitative agglutination	Other biological fluids, clinical sample
07.0 MICROBIOLOGY	07.5 Microbiology – parasitology	Research and identification of parasites	Parasite culture	Secretion, clinical sample
07.0 MICROBIOLOGY	07.5 Microbiology – parasitology	Research and identification of parasites	Microscopic examination including preparation	Blood and derived products, feces, fresh tissue, and other biological fluids, CSF
07.0 MICROBIOLOGY	07.5 Microbiology – parasitology	Research and identification of parasites	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	Autopsies; ultrastructural morphological observation of tissue and cellular components; evaluation of the proportion of specific components/antigens/enzymes	Microscopic examination including preparation	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	Autopsies; ultrastructural morphological observation of tissue and cellular components; evaluation of the proportion of specific components/antigens/enzymes	Macroscopic examination including preparation	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	Autopsies; ultrastructural morphological observation of tissue and cellular components; evaluation of the proportion of specific components/antigens/enzymes	Immunohistochemistry	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.3 Pathology – cytology	Morphological observation of cellular constituents	Microscopic examination including preparation	Secretions, other biological fluids

# <u>Notes</u>

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 <u>www.scc.ca</u>.

Elias Rafoul Vice President, Accreditation Services Publication on: 2024-08-19



