

# MEDICAL LABORATORY ACCREDITATION PROGRAM

# **Scope of Accreditation**

Legal Name of Accredited Laboratory: Département clinique de médecine de

laboratoire du CIUSSS de l'Estrie -Centre hospitalier universitaire de Sherbrooke (CHUS) (site Hôpital

Fleurimont)

Contact name: Sylvie Martel, Clinico-administrative Director

Address: 3001, 12th Avenue N., Sherbrooke

(Québec)J1H 5N4

Telephone: 819-346-1110

Website: <a href="https://www.santeestrie.qc.ca/accueil">https://www.santeestrie.qc.ca/accueil</a>

Email: <u>sylvie.martel.ciussse-chus@ssss.gouv.qc.ca</u>

SCC File Number:	151195
Provider:	BNQ-EL
Provider File Number:	56566-1
Accreditation Standard(s):	ISO 15189:2012 Medical laboratories – Requirements for quality and competence CAN/CSA-Z902-20 Blood and blood components
Program Specialty Area:	Medical
Initial Accreditation:	2021-12-20
Most Recent Accreditation:	2023-12-20
Accreditation Valid to:	2025-12-20

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.

- Hôtel-Dieu de Sherbrooke, 580, Bowen S. St., Sherbrooke (Québec) J1G 2E8 (CCN N°: 151196/ BNQ N°: 56567-1)
- CSSS de Memphrémagog, 50, rue Saint-Patrice Est, Magog (Québec) J1X 3X3 (CCN Nº: 151197/BNQ Nº: 56568-1)
- Hôpital, CLSC et Centre d'hébergement d'Asbestos, 475, 3<sup>rd</sup> Avenue, Val-des-Sources (Québec) J1T 3N4 (CCN N°: 151198/BNQ N°: 56569-1)
- CSSS de la MRC-de-Coaticook, 138, Jeanne-Mance St., Coaticook, (Québec) J1A 1W3 (CCN №: 151199/BNQ №: 56570-1)
- CSSS du Granit, 3569, Laval St., Lac-Mégantic (Québec) G6B 1A5 (CCN Nº: 151200/BNQ Nº: 56571-1)
- Hôpital de Granby, 205, Leclerc W. Blvd., Granby (Québec) J2G 1T7 (CCN №: 151201/BNQ №: 56572-1)
- Hôpital Brome-Missisquoi-Perkins, 950, Principale St., Cowansville (Québec) J2K 1K3 (CCN №: 151202/BNQ №: 56573-1)

#### 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

#### 02.0 MOLECULAR BIOLOGY

02.1	MOLECULAR DIAGNOSIS – VARIOUS
02.2	MOLECULAR DIAGNOSIS – HEMATOLOGY
02.3	MOLECULAR DIAGNOSIS – INFECTIOUS DISEASES
02.4	MOLECULAR DIAGNOSIS – HEREDITARY DISEASES
02.5	MOLECULAR DIAGNOSIS - ONCOLOGY

# 03.0 MATERNAL SERUM SCREENING

03.2 MATERNAL SERUM SCREENING - NEONATAL





#### **SCOPE OF ACCREDITATION**

# 04.0 GENETICS / CYTOGENETICS

04.1 GENETICS – BIOCHEMISTRY04.2 GENETICS – CYTOGENETICS

# 05.0 HEMATOLOGY

05.1	HEMATOLOGY – CYTOCHEMISTRY
05.2	HEMATOLOGY - CYTOLOGY
05.3	HEMATOLOGY - ERYTHROCYTIC
05.5	HEMATOLOGY - HEMOSTASIS
05.6	HEMATOLOGY - IMMUNOCYTOMETRY
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	MICRORIOLOGY - PARASITOLOGY

# 08.0 ANATOMICAL PATHOLOGY

08.1	PATHOLOGY — CLINICAL
08.2	PATHOLOGY – FERTILITY
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	Immunochromatography	Secretions
			Reflectance	Urine
			Refractometry	Urine, other biological fluids
		Osmolality measurement	Cryoscopic Osmometry	Blood and derived products, feces, urine, other biological fluids





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
			Atomic absorption	Blood and derived products, urine
			Chromatography	Blood and derived products
			Co-oximetry	Blood and derived products
			Electrochemistry	CSF, blood and derived products, secretions, feces, urine, other biological fluids
			Electrophoresis	CSF, urine, blood and derived products
			Microscopic examination including preparation	Biological fluid, urine
		Research, identification and	Gravimetry	Feces
		concentration determination of organic and inorganic molecules and enzyme	Modified radial immunodiffusion	Blood and derived products, urine
		activity	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Biological fluid, CSF, blood and derived products, feces
			Immunoassay - turbidimetry	CSF, blood and derived products, urine
			Visual reading	Feces
			Precipitation	Blood and derived products
			Mass spectroscopy	Blood and derived products
			Spectrophotometry	Clinical samples, CSF, blood and derived products, urine and other biological fluids
			Infrared spectrometry	Stones
		Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Immunochromatography	Blood and derived products, secretions, urine and other biological fluids
	01.2 Biochemistry – hormonal		Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products, secretions, urine and other biological fluids
immuno		,	Mass spectroscopy	Blood and derived products, urine
	01.3 Biochemistry – immunology	Research, identification and concentration determination of organic and inorganic	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	illinatiology	molecules and enzyme activity	Immunoassay - turbidimetry	
		Research, identification and/or determination of the concentration of	Immunoassay - turbidimetry	Blood and derived products
			Mass spectroscopy	Blood and derived products
	xenobiotics/drugs	Spectrophotometry	Blood and derived products	
			Atomic absorption	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		Research, identification	Immunoassay - turbidimetry	Urine
	01.5 Biochemistry – toxicology	and/or determination of the concentration of toxic substances or analytes	Spectrophotometry	Blood and derived products, urine
	02.1 Molecular diagnosis – various	Molecular techniques for biomedical analysis		DNA or RNA from clinical sample
	02.2 Molecular diagnosis – hematology	Genotyping and cell typing (erythrocytes, platelets, granulocytes, etc.)	Detection of nucleic acids	DNA or RNA from clinical sample
	02.3 Molecular diagnosis – infectious diseases	Research and identification and/or determination of the concentration (quantification) of viral, bacterial and fungal nucleic acids		DNA or RNA from clinical sample
02.0 MOLECULAR BIOLOGY	02.4 Molecular diagnosis – hereditary diseases	Characterization and/or quantification of molecular anomalies	Next generation sequencing	DNA or RNA from clinical sample
		Characterization and/or	Detection of nucleic acids	DNA or RNA from clinical sample
	02.5 Molecular diagnosis – oncology	anomalies: detection of mutations, inversions, translocations, methylations, deletions, etc.	Molecular in situ hybridization (CISH, FISH)	Tissue/cell blocks (paraffin, others), cells, fresh tissue
			Next generation sequencing	Tissue/cell blocks (paraffin, others), cells, fresh tissue
		Characterization and/or quantification of molecular anomalies	Detection of nucleic acids	DNA or RNA from clinical sample
03.0 MATERNAL SERUM SCREENING	03.2 Maternal serum screening - neonatal	Screening for diseases or abnormalities	Chromatography	Urine
	04.1 Genetics – biochemistry	Expression analysis and/or mutation-related functional tests	Manual assay (enzymes, metabolites)	Urine
			Mass spectroscopy	Cells, CSF, blood and derived products, fresh tissue, urine, amniotic fluid, other biological fluids
			Spectrophotometry	Blood and by-products, urine, CSF
			Chromatography	Urine
04.0 GENETICS - CYTOGENETICS		Karyotype - Numerical and morphological study of chromosomes	Microscopic examination including preparation	Amniotic fluid, marrow, blood and derived products, fresh tissue
	04.2 Genetics – cytogenetics		Cell culture	Cells, fresh tissue
		Genetic diagnosis	Molecular hybridization techniques (microbeads)	Cells, marrow
		Search for chromosomal and/or molecular abnormalities	Comparative genomic hybridization (CGH)	Blood and derived products, cells
			Molecular in situ hybridization (CISH, FISH)	Cells, blood and derived products, fresh tissue





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
			Detection of nucleic acids	Cells, blood and derived products, fresh tissue
	05.1 Hematology –	Determination of hematocytochemistry parameters	Microscopic examination	Blood and derived products, marrow
	cytochemistry	Hemogram, research, identification and/or cells quantification	including preparation	Blood and derived products, marrow
			Calculation	Blood and derived products
			Flow cytometry	Blood and derived products
	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Microscopic examination including preparation	CSF, marrow, blood and derived products, urine, secretions, other biological fluids
			Impedance measurement	Blood and derived products
			Spectrophotometry	Blood and derived products
		Red blood cell aggregation technique	Precipitation	Blood and derived products
	05.3 Hematology – erythrocytic	Physical characterization	Viscometry	Blood and derived products
		Detection and quantification of markers/glycoproteins/enzym	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
05.0 HEMATOLOGY		es	Spectrophotometry	Blood and derived products
US.O REMATOLOGI		Search for cellular abnormalities	Microscopic examination including preparation	Marrow, blood and derived products
			Visual reading	Blood and derived products
		Research and determination of hemoglobin concentration	Alkaline denaturation	Feces, secretions
			Electrophoresis	Blood and derived products
			Spectrophotometry	Blood and derived products
			Coagulometry	Blood and derived products
			Immunoassay - turbidimetry	Blood and derived products
		Determination of hemostasis	Visual reading	Blood and derived products
		parameters	Chromogenic method	Blood and derived products
	05.5 Hematology –		Chronometric method	Blood and derived products
	hemostasis		Precipitation	Blood and derived products
		Bleeding time		Blood and derived products
		Platelet tests, search for and determination of heparindependent antibody concentration	Aggregometry	Blood and derived products
	05.6 Hematology – immunocytometry	Hematocytological phenotyping	Flow cytometry	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		Search for cellular abnormalities	Precipitation	Blood and derived products
		of the antibody concentration	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		to be validated	Immunoassay - fluorescence	Blood and derived products
	05.7 Hematology – immunology	Research, identification and/or determination of anticoagulants, antibodies, to	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		be validated	Immunoassay - fluorescence	Blood and derived products
		Research, identification and/or determination of the concentration of proteins,	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		anticoagulants, antibodies	Immunoassay - turbidimetry	Blood and derived products
		Erythrocyte antigen detection and determination	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	Research and determination of erythrocyte antigens (for ABO, antibodies)	Enzymatic method	Blood and derived products
		Determination of blood types	Immunological method of hemagglutination and derivative	Blood and derived products
	07.1 Microbiology – bacteriology	Characterization of the sensitivity of bacteria to different substances	Phenotypic determination: sensitivity tests	Isolate
		Preparation for bacterial research and identification	Bacterial culture	Secretions, CSF, blood and derived products, isolate, feces, urine, clinical specimen or biological fluid
		Research and identification of bacteria	Phenotypic determination by mass spectrometry	Isolate
			Microscopic examination including preparation	Feces, secretions, isolate, clinical sample
07.0 MICROBIOLOGY		Research and identification of toxins, enzymes, antibodies	Phenotypic determination: biochemical characterization	Isolate
		and bacterial antigens		Feces, urine
		Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Feces, urine
	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
			Qualitative or quantitative agglutination	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
			Enzyme immunoassays (chemiluminescence, EIA and derivatives)	
			Immunoassay - fluorescence	Blood and derived products
			Mycobacterial culture	Clinical samples, blood and derived products, fresh tissue
	07.3 Microbiology – mycobacteriology	Research and identification of mycobacteria	Microscopic examination including preparation	Clinical samples, blood and derived products, fresh tissue
			Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
			Fungal culture	Blood and derived products, clinical sample
		Research and identification of fungi and yeast	Phenotypic determination: biochemical characterization	Clinical sample
	07.4 Microbiology –	Tungi and yeast	Microscopic examination including preparation	Blood and derived products, clinical sample
	mycology		Immunoassay - fluorescence	Clinical sample
		Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Qualitative or quantitative agglutination	Biological fluid
			Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Clinical sample
	07.5 Microbiology – parasitology	Research and identification of parasites	Microscopic examination including preparation	Blood and derived products
		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
		Autopsies; ultrastructural morphological observation of	Microscopic examination including preparation	Fresh tissue
		tissue and cellular components; evaluation of	Histo-enzymology	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	the proportion of specific components/antigens/enzym es	Immunohistochemistry	Fresh tissue
		Evaluation of the proportion of specific constituents/antigens/enzym es	Immunoassay - fluorescence	Fresh tissue
	08.2 Pathology – fertility	Morphological study and cell identification		Semen
	08.3 Pathology – cytology	Morphological observation of cellular constituents	Microscopic examination including preparation	Cells
		Research		Cells





# **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: 2023-12-22