

## MEDICAL LABORATORY ACCREDITATION PROGRAM

# **Scope of Accreditation**

Legal Name of Accredited Laboratory: Département de médecine de laboratoire

du CHU de Québec – Université Laval

(site CENTRE HOSPITALIER DE

L'UNIVERSITE LAVAL)

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SCC File Number:	151142
Provider:	BNQ-EL
Provider File Number:	56432-1
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:	2020-10-16
Most Recent Accreditation:	2023-09-30
Accreditation Valid to:	2025-10-16

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.

- Hôpital de l'Archipel, 430, chemin Principal, Cap-aux-Meules (Québec) G4T 1R9 (No CCN : 151143 / No BNQ : 56433-1).
- Hôpital Jeffery Hale, 1250, chemin Sainte-Foy, Québec (Québec) G1S 2M6 (No CCN : 151144 / No BNQ : 56434-1),
- Hôpital régional de Portneuf, 700, rue Saint-Cyrille, Saint-Raymond (Québec) G3L 1W1 (No CCN : 151145 / No BNQ : 56435-1),
- Hôpital Chauveau, 11999, rue de l'Hôpital, Québec (Québec) G2A 2T7 (No CCN : 151146 / No BNQ : 56436-1),
- Hôpital de Saint-Anne-de-Beaupré, 11000, rue des Montagnards, Beaupré (Québec) G0A 1E0 (No CCN: 151147 / No BNQ: 56437-1),
- Hôpital de La Malbaie, 303, rue Saint-Étienne, La Malbaie (Québec) G5A 1T1 (No CCN : 151148 / No BNQ : 56438-1),
- Hôpital de Baie-Saint-Paul, 88, rue Racine, Baie-Saint-Paul (Québec) G3Z 0K3 (No CCN : 151149 / No BNQ : 56439-1),
- Hôpital du Saint-Sacrement, 1050, chemin Sainte-Foy, Québec (Québec) G1S 4L8 (No CCN : 151151 / No BNQ : 56441-1),
- Hôtel-Dieu de Québec, 11, Côte du Palais, Québec (Québec) G1R 2J6 (No CCN : 151152 / No BNQ : 56442-1).
- Hôpital Saint-François d'Assise, 10, rue de l'Espinay, Québec (Québec) G1L 3L5 (No CCN : 151153 / No BNQ : 56443-1),
- -Hôpital de l'Enfant-Jésus, 1401, 18° Rue, Québec (Québec) G1J 1Z4 (No CCN : 151154 / No BNQ : 56444-1).
- Institut universitaire de cardiologie et de pneumologie de Québec, 2725, chemin Sainte-Foy, Québec (Québec) G1V 4G5 (No CCN : 151155 / No BNQ : 56445-1),





### **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\*

- 02.2 MOLECULAR DIAGNOSIS HEMATOLOGY
- 02.3 MOLECULAR DIAGNOSIS INFECTIOUS DISEASES
- 02.4 MOLECULAR DIAGNOSIS HEREDITARY DISEASES
- (\*) This discipline covers tests subject to ISO 22870; see detailed scope

#### 03.0 MATERNAL SERUM SCREENING

03.1 MATERNAL SERUM SCREENING - PRENATAL

#### 04.0 GENETICS / CYTOGENETICS

04.1 GENETICS - BIOCHEMISTRY

### 05.0 HEMATOLOGY\*

- 05.2 HEMATOLOGY CYTOLOGY
- 05.3 HEMATOLOGY ERYTHROCYTIC
- 05.4 HEMATOLOGY GRAFTS
- 05.5 HEMATOLOGY HEMOSTASIS
- 05.6 HEMATOLOGY IMMUNOCYTOMETRY
- 05.7 HEMATOLOGY IMMUNOLOGY
- (\*) This discipline covers tests subject to ISO 22870; see detailed scope

#### 06.0 TRANSFUSION MEDICINE

#### 07.0 MICROBIOLOGY

- 07.1 MICROBIOLOGY BACTERIOLOGY
- 07.2 MICROBIOLOGY IMMUNOSEROLOGY
- 07.4 MICROBIOLOGY MYCOLOGY



# **SCOPE OF ACCREDITATION**

07.5 MICROBIOLOGY – PARASITOLOGY

### 08.0 ANATOMICAL PATHOLOGY

08.1 PATHOLOGY – CLINICAL08.2 PATHOLOGY – FERTILITY

# **DETAILS OF SCOPE OF ACCREDITATION**

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		Osmolality measurement	Cryoscopic Osmometry	Blood and derived products, urine
			Chromatography	Blood and derived products
			Flow cytometry	Urine
			Electrochemistry	Blood and derived products, urine, other biological fluids
			Microscopic examination including preparation	Urine
			Immunochromatography	Secretions
	01.1 Biochemistry – clinical		Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		Research, identification and	Immunoassay - fluorescence	Blood and derived products
		concentration determination of organic and inorganic molecules and enzyme activity	Nephelometry	Blood and derived products, urine
01.0 BIOCHEMISTRY			Reflectance	Urine
			Refractometry	Urine
			Spectrophotometry	Blood and blood products, urine, CSF, other biological fluids
	01.2 Biochemistry – hormonal		Immunochromatography	Urine
			Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products, urine, other biological fluids
	01.3 Biochemistry – immunology			Blood and derived products
			Nephelometry	Blood and derived products
	01.4 Biochemistry – medication	Research, identification and/or determination of the concentration of xenobiotics / drugs	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
			Immunoassay - turbidimetry	Blood and derived products
			Spectrophotometry	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
	01.5 Biochemistry – toxicology		Immunochromatography	Urine
		Research, identification and/or determination of the concentration of toxic substances or analytes	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Urine
			Spectrophotometry	Blood and derived products
	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	AmnioTest Blood gases and electrolytes Blood sugar Hemoglobinemia	Blood and derived products, urine
	02.2 Molecular Diagnostics Hematology	HLA genotyping, chimerism, genetic polymorphisms	Detection of nucleic acids	DNA or RNA from clinical sample
		Identification of specific microorganisms	Conventional sequencing	Blood and derived products
	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	Clinical specimen, isolate, urine, CSF, fresh tissue
02.0 MOLECULAR BIOLOGY	02.4 Molecular diagnosis of hereditary disease	Characterization and/or quantification of molecular anomalies	Detection of nucleic acids	DNA or RNA from clinical sample
			Conventional sequencing	DNA or RNA from clinical sample
	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	SARS-CoV-2	Clinical sample
03.0 PRENATAL SCREENING	03.1 Prenatal screening	Screening for diseases or abnormalities	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
04.0 GENETICS - CYTOGENETICS	04.1 Biochemistry genetics	Expression analysis and/or functional tests associated with a mutation	Spectrophotometry	Blood and derived products
	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Microscopic examination including preparation	Blood and blood products, bone marrow, CSF
			Impedance measurement	Blood and blood products, bone marrow, other biological fluids
		Red blood cell aggregation technique	Precipitation	Blood and derived products
		Search for cellular abnormalities	Visual reading	Blood and derived products
05.0 HEMATOLOGY	05.3 Hematology – erythrocytic		Chromatography	Blood and derived products
		Research and determination of hemoglobin concentration	Alkaline denaturation	Feces
			Spectrophotometry	Blood and derived products
		Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	05.4 Hematology – transplant	HLA genotyping, chimerism, genetic polymorphisms	Cell complements sensitivity test	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		Research, identification and/or concentration determination of antibodies and other protein compounds		Blood and derived products
		Search, identification and/or determination of antibody concentration	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
		Determination of hemostasis parameters	Calculation	Blood and derived products
			Coagulometry	Blood and derived products
			Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	05.5 Hematology – hemostasis		Chromogenic method	Blood and derived products
			Turbidimetry	Blood and derived products
		Bleeding time		Blood and derived products
		Platelet tests, search for and determination of heparin-dependent antibody concentration	Aggregometry	Blood and derived products
		Comparative test	Flow cytometry	Blood and derived products
	05.6 Hematology –	Hematocytological phenotyping		Blood and derived products
	immunocytometry  05.7 Hematology – immunology	Research, identification and/or determination of the concentration of antibodies and other protein compounds		Blood and derived products
		Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
			Immunoassay - fluorescence	Blood and derived products, other biological fluids
			Nephelometry	Blood and derived products
	РОСТ	Research, identification and concentration determination of organic and inorganic molecules and enzyme activity	Activated clotting time (ACT)	Blood and derived products
	06.0 Transfusion medicine	Comparative test	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE		Research and determination of erythrocyte antigens; determination of blood groups		Blood and derived products
	07.1 Microbiology – bacteriology	Characterization of the sensitivity of bacteria to different substances	Phenotypic determination: sensitivity tests	Isolate
07.0 MICROBIOLOGY		Preparation for bacterial research and identification	Cell culture	Blood and derived products, clinical specimen, urine, feces,
			Microscopic examination including preparation	Blood and derived products, clinical specimen, CSF, secretions, urine, other biological fluids





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		Research and identification of bacteria	Phenotypic determination by mass spectrometry	Isolate
			Microscopic examination including preparation	Isolate, clinical specimen, blood and derived products, urine
		Research and identification of toxins, enzymes, antibodies and bacterial antigens	Phenotypic determination: biochemical characterization	Isolate
	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
			Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
	07.4 Microbiology – mycology	Research and identification of fungi and yeast	Phenotypic determination by mass spectrometry	Isolate
	07.5 Microbiology – parasitology	Research and identification of parasites	Calculation	Blood and derived products
			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)	Secretions, urine
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
	08.2 Pathology – fertility	Morphological study and cell identification	Microscopic examination including preparation	Semen

# **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: 2024-10-10