

MEDICAL LABORATORY ACCREDITATION PROGRAM

Scope of Accreditation

Legal Name of Accredited Laboratory:	Département clinique de médecine de laboratoire du Centre hospitalier universitaire Sainte-Justine
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SCC File Number:	151127
Provider:	BNQ-EL
Provider File Number:	56656-1
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:	2021-04-19
Most Recent Accreditation:	2021-04-19
Accreditation Valid to:	2025-04-19
Medical Principal Disciplines:	See below

*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 québécois de génomique clinique (CQGC), 3175, chemin de la Côte-Ste-Catherine, Montréal (Québec) H3T 1C5 (No CCN : 151211/No BNQ : 59609-1), numéro de laboratoire accrédité : 963

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 in APPENDIX A

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

- 03.1 MATERNAL SERUM SCREENING - PRENATAL

04.0 GENETICS / CYTOGENETICS

- 04.1 GENETICS – BIOCHEMISTRY
- 04.2 GENETICS – CYTOGENETICS

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

05.6 HEMATOLOGY – IMMUNOCYTOMETRY

05.7 HEMATOLOGY – IMMUNOLOGY

(*) This discipline covers tests subject to ISO 22870; see detailed scope in APPENDIX A

06.0 TRANSFUSION MEDICINE

07.0 MICROBIOLOGY

07.1 MICROBIOLOGY – BACTERIOLOGY

07.2 MICROBIOLOGY – IMMUNOSEROLOGY

07.4 MICROBIOLOGY – MYCOLOGY

07.5 MICROBIOLOGY – PARASITOLOGY

07.6 MICROBIOLOGY – VIROLOGY

08.0 ANATOMICAL PATHOLOGY

08.1 PATHOLOGY – CLINICAL

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	Refractometry	Urine, other biological fluids
		Measurement of osmolality	Cryoscopic osmometry	Blood and blood products, urine
		Research, identification and determination of the concentration of organic and inorganic molecules and enzymatic activity	Calculation	Blood and blood products
			Liquid chromatography	Blood and blood products
			Liquid Chromatography and Tandem Mass Spectrometry	Blood and blood products
			Co-oximetry	Blood and blood products
			Electrochemistry	Breath, Blood and blood products, urine, secretions, other biological fluids
			Microscopic examination including preparation	Urine
			Gravimetry	Urine
			Immunochemistry	Other biological fluids
			Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products, feces, other biological fluids
			Immunoassay - turbidimetry	Blood and blood products, urine, other biological fluids

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
			Visual examination	Clinical specimen, blood and blood products, feces, urine, other biological fluids
			Chromogenic method	Feces, other biological fluids
			Reflectance	Urine
			Spectrophotometry	Blood and blood products, urine, feces, CSF, other biological fluids
			Turbidimetry	Urine, CSF, other biological fluids
	01.2 Biochemistry – hormonal	Research, identification and determination of the concentration of organic and inorganic molecules and enzymatic activity	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products
			Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products
	01.3 Biochemistry – immunology	Research, identification and determination of the concentration of organic and inorganic molecules and enzymatic activity	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products
	01.4 Biochemistry – medication	Research, identification and/or determination of the concentration of xenobiotics / drugs.	Liquid chromatography	Blood and blood products
			Liquid Chromatography and Tandem Mass Spectrometry	Blood and blood products
			Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products
			Immunoassay - turbidimetry	Blood and blood products
			Spectrophotometry	Blood and blood products
	01.5 Biochemistry – toxicology	Research, identification and/or determination of the concentration of toxic substances or analytes.	Gas chromatography and mass spectrometry	Blood and blood products
			Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products, urine, CSF, other biological fluids
POCT	Research, identification and determination of the concentration of organic and inorganic molecules and enzymatic activity	Activated clotting time (ACT) Urinalysis (strips) Analysis of H ₂ and CH ₄ in the breath (Breath test) Ketonemia Chloride in sweat Urinary specific gravity Blood gases and electrolytes Blood sugar Hemoglobinemia Pregnancy test	Blood and blood products, urine	
02.0 MOLECULAR BIOLOGY	02.1 Molecular diagnosis – various	Various molecular techniques in biomedical analyzes	Detection of nucleic acids	Clinical sample DNA or RNA
	02.2 Molecular diagnosis – hematology	Detection of nucleotide variations	Conventional sequencing	Clinical sample DNA or RNA
		Genotyping and cell typing (erythrocytes, platelets, granulocytes, etc.)	Detection of nucleic acids	Clinical sample DNA or RNA
		HLA genotyping, chimerism, genetic polymorphisms		

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)	
	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	Other biological fluids, fresh tissue, clinical sample, secretions CSF, bone marrow, feces, urine	
	02.4 Molecular diagnosis – hereditary diseases	Characterization and/or quantification of molecular anomalies	Detection of nucleic acids	Clinical sample DNA or RNA	
			High throughput sequencing	Clinical sample DNA or RNA	
			Conventional sequencing	Clinical sample DNA or RNA	
		Detection of nucleotide variations	Conventional sequencing	Clinical sample DNA or RNA	
	02.5 Molecular diagnosis – oncology	Characterization and/or quantification of molecular anomalies: detection of mutations, inversions, translocations, methylations, deletions	Detection of nucleic acids	Clinical sample DNA or RNA	
			Detection of nucleic acids	Clinical sample DNA or RNA	
			Conventional sequencing	Clinical sample DNA or RNA	
	03.0 MATERNAL SERUM SCREENING	03.1 Maternal serum screening - prenatal	Screening for diseases or abnormalities	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products
	04.0 GENETICS / CYTOGENETICS	04.1 Genetics – biochemistry	Research, identification and determination of the concentration of organic molecules and enzymatic activity	Immunoassay - radiometric (RIA and derivatives)	Blood and blood products, cells
Gas chromatography and mass spectrometry				Blood and blood products, urine	
Liquid chromatography				Blood and blood products, cells, CSF, urine	
Liquid Chromatography and Tandem Mass Spectrometry				Blood and blood products, urine	
Fluorometry				Blood and blood products, cells, fresh tissue	
Immunoblotting				Cells, fresh tissue	
Visual examination				Urine	
Spectrophotometry				Blood and blood products, cells, fresh tissue, urine	
04.2 Genetics – cytogenetics		Characterization and/or quantification of molecular anomalies	Microscopic examination including preparation	Blood and blood products, cells, fresh tissue, clinical sample DNA or RNA, bone marrow, other biological fluids	
			Cellular culture	Cells	
		Karyotype – Numerical and morphological study of chromosomes	Microscopic examination including preparation	Blood and blood products, cells, fresh tissue, clinical sample DNA or RNA, bone marrow, other biological fluids	
			Cellular culture	Blood and blood products, cells, fresh tissue, bone marrow, other biological fluids	
Genetic diagnosis		Cellular culture	Blood and blood products, cells, fresh tissue, bone marrow, other biological fluids		
Search for chromosomal and/or molecular abnormalities		Comparative Genomic Hybridization (CGH)	Blood and blood products, cells, fresh tissue, frozen tissue, bone marrow, other biological fluids		

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)	
			Molecular in situ hybridization (CISH, FISH)	Blood and blood products, cells, fresh tissue, clinical sample DNA or RNA, bone marrow, other biological fluids	
05.0 HEMATOLOGY	05.1 Hematology – cytochemistry	Hemogram, research, identification and/or cells quantification	Microscopic examination including preparation	Blood and blood products, cells, bone marrow	
	05.2 Hematology – cytology	Hemogram, research, identification and/or cells quantification	Calculation	Blood and blood products	
			Microscopic examination including preparation	Blood and blood products, urine, bone marrow, CSF	
		Red blood cell aggregation technique	Impedanceometry	Blood and blood products	
	05.3 Hematology – erythrocytic	Search for cell abnormalities	Microscopic examination including preparation	Blood and blood products	
			Visual examination	Blood and blood products	
		Research and determination of hemoglobin concentration	Alkaline denaturation	Feces	
	05.4 Hematology – grafts	Cell culture with or without function assessment	Electrophoresis	Blood and blood products	
			Cellular culture	Blood and blood products, bone marrow	
			Determination of T cell proliferation	Flow cytometry	Blood and blood products, bone marrow
	05.5 Hematology – hemostasis	Determination of hemostasis parameters	Hematocytological phenotyping	Molecular hybridization techniques (microbeads)	Blood and blood products, bone marrow
			Aggregometry	Blood and blood products	
			Coagulometry	Blood and blood products	
			Electrophoresis and immunoblotting	Blood and blood products	
			Fluorometry	Blood and blood products	
			Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products	
			Immunoassay - turbidimetry	Blood and blood products	
			Visual examination	Blood and blood products	
			Chromogenic method	Blood and blood products	
			Bleeding time	Chromogenic method	Blood and blood products
	05.6 Hematology – immunocytometry	Platelet tests, search for and determination of heparin-dependent antibody concentration	Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Precipitation	Blood and blood products
			Research, identification and/or determination of the concentration of antibodies and other protein compounds	Flow cytometry	Blood and blood products

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)	
	05.7 Hematology – immunology	Activity determination	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products	
			Spectrophotometry	Blood and blood products	
		Comparative test	Flow cytometry	Blood and blood products	
		IL-12 production induced by interferon Gamma	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products	
		IL-6 production induced by TLR activators		Blood and blood products	
		Production of interferon Gamma induced by IL12		Blood and blood products	
		TNF production induced by TLR activators		Blood and blood products	
		Proliferation of T cells in the presence of PHA	Flow cytometry	Blood and blood products	
		Research and determination of the concentration of proteins, anticoagulants, antibodies	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Blood and blood products	
		Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies	Immunoassay - fluorescence	Blood and blood products	
			Immunoassay - turbidimetry	Blood and blood products	
			Precipitation	Blood and blood products	
Signaling by TOLL receptors: Detection by CD62L cleavage	Flow cytometry	Blood and blood products			
06.0 TRANSFUSION MEDICINE	06.0 TRANSFUSION MEDICINE	Research and determination of erythrocyte antigens and/or antibodies; determination of blood groups	Immunological method of haemagglutination and derivatives	Blood and blood products, cells	
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	Characterization of the sensitivity of bacteria to different substances	Phenotypic determination: susceptibility tests	Isolate	
		Preparation for bacterial research and identification	Bacterial culture	Clinical specimen, fresh tissue, CSF, bone marrow, secretions, feces, urine, other biological fluids	
			Cellular culture	Clinical specimen, secretions, other biological fluids	
		Research and identification of toxins, enzymes, antibodies and bacterial antigens	Phenotypic determination: biochemical characterization	Isolate	
			Enzymatic immunoassay (chemiluminescence, EIA and derivatives)	Feces	
		Research and identification of bacteria	Microscopic examination including preparation	Clinical specimen, blood and blood products, fresh tissue, CSF, secretions, other biological fluids	
		07.2 Microbiology – immunoserology	Antibody avidity	Enzymatic immunoassay (chemiluminescence, EIA and derivatives)	Blood and blood products
			Research, identification and/or determination of the concentration of	Qualitative or quantitative agglutination	Blood and blood products

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)	
		antibodies and/or antigens specific to infectious agents	Enzymatic immunoassay (chemiluminescence, EIA and derivatives)	Blood and blood products	
			Immunoassay - fluorescence	<i>Blood and blood products</i>	
	07.4 Microbiology – mycology	Research and identification of fungi and yeasts	Characterization of the sensitivity of infectious agents to different substances	Phenotypic determination: sensitivity tests	Isolate
			Culture	Clinical specimen, fresh tissue, CSF, secretions, other biological fluids	
			Microscopic examination including preparation	Clinical specimen, fresh tissue, CSF, secretions, other biological fluids	
	07.5 Microbiology – parasitology	Research and identification of parasites	Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Enzymatic immunoassay (chemiluminescence, EIA and derivatives)	Blood and blood products, CSF
			Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents	Immunochromatography	Blood and blood products, secretions
	07.6 Microbiology – virology	Research and identification of specific viruses	Cell culture		Clinical specimen, fresh tissue, CSF, secretions, urine, feces, other biological fluids
			Enzyme immunoassay (chemiluminescence, EIA and derivatives)		Feces
			Immunoassay - fluorescence		Clinical specimen
	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	Tissue/cell blocks (paraffin, others), cells, fresh tissue
				Histo-enzymology	Fresh tissue
Immunohistochemistry				Fresh tissue	
Evaluation of the proportion of specific constituents/ antigens/ enzymes			Immunoassay - fluorescence	Fresh tissue	
Research, identification and quantification of specific constituents			Flow cytometry	Tissue/cell blocks (paraffin, others)	

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 www.scc.ca.

Elias Rafoul
Vice President, Accreditation Services
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APPENDIX A

SITES UNDER THE RESPONSIBILITY OF THE ACCREDITED LABORATORY

Département clinique de médecine de laboratoire du Centre hospitalier universitaire Sainte-Justine
 3175, chemin de la Côte-Ste-Catherine
 Montréal, Québec
 H3T 1C5

Site	Tests
Centre de Réadaptation Marie-Enfant (CRME) Adresse : 5200, rue Bélanger Montréal QC H1T 1C9	1 Urinalysis (strips)
	2 Blood sugar