

MEDICAL LABORATORY ACCREDITATION PROGRAM

Scope of Accreditation

Legal Name of Accredited Laboratory: Département clinique de médecine de laboratoire de l'HÔTEL-DIEU DE LÉVIS (site Hôpital de Thetford Mines)

Contact name: Mélanie Bernard

Address: 1717 rue Notre-Dame Est
Thetford Mines (Québec) G6G 2V4

Telephone: 418-338-7777, poste 54324

Website: <https://www.cisss-ca.gouv.qc.ca/accueil/>

Email: melanie.bernard@ssss.gouv.qc.ca

SCC File Number:	151109
Provider:	BNQ-EL
Provider File Number:	56728-1
Accreditation Standard(s):	ISO 15189:2012 <i>Medical laboratories – Requirements for quality and competence</i> ; ISO 22870:2016 <i>Point of care testing (POCT) – Requirements for quality and competence</i> ; CAN/CSA-Z902-20 <i>Blood and blood components</i>
Program Specialty Area:	Medical
Initial Accreditation:	2021-03-26
Most Recent Accreditation:	2021-03-26
Accreditation Valid to:	2025-03-26
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.

- Hôtel-Dieu de Lévis, 143, rue Wolfe, Lévis (Québec) G6V 3Z1
(N° CCN : 151107/N° BNQ : 56726-1)
- Centre Paul-Gilbert – Centre d’hébergement de Charny, 9330, boulevard du Centre-Hospitalier, Lévis (Québec) G6X 1L6 (N° CCN : 151108/N° BNQ : 56727-1)
- Hôpital de Montmagny, 350, boulevard Taché Ouest, Montmagny (Québec) G5V 3R8
(N° CCN : 151110/N° BNQ : 56729-1)
- Hôpital de Saint-Georges, 1515, 17^e Rue, Saint-Georges (Québec) G5Y 4T8
(N° CCN : 151111/N° BNQ : 56730)

SCOPE OF ACCREDITATION

01.0 BIOCHEMISTRY *

- 01.1 BIOCHEMISTRY – CLINICAL
- 01.2 BIOCHEMISTRY – HORMONAL
- 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

- 02.3 MOLECULAR DIAGNOSIS – INFECTIOUS DISEASES

05.0 HEMATOLOGY

- 05.2 HEMATOLOGY – CYTOLOGY
- 05.5 HEMATOLOGY – HEMOSTASIS

06.0 TRANSFUSION MEDICINE

07.0 MICROBIOLOGY

- 07.1 MICROBIOLOGY – BACTERIOLOGY
- 07.2 MICROBIOLOGY – IMMUNOSEROLOGY

08.0 ANATOMICAL PATHOLOGY

- 08.1 PATHOLOGY – CLINICAL
- 08.2 PATHOLOGY – FERTILITY

DETAILS OF SCOPE OF ACCREDITATION

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30032 – pancreatic amylase	Spectrophotometry	Blood, blood products
		30010 -Lactic acid (colorimetric)	Spectrophotometry	Blood, blood products
		30013 – Uric Acid	Spectrophotometry	Blood, blood products
		30016 - Alanine aminotransferase (ALT)	Spectrophotometry	Blood, blood products
		30017 - Albumin	Spectrophotometry	Blood, blood products
		30029 - Ammonia	Spectrophotometry	Blood, blood products
		30030 – Total amylase	Spectrophotometry	Blood, blood products
		30060 - aspartate transaminase (AST)	Spectrophotometry	Blood, blood products
		30083 – Direct bilirubine (conjugate)	Spectrophotometry	Blood, blood products
		30084 – Total bilirubin	Spectrophotometry	Blood, blood products
		30085 - BNP (Brain Natriuretic Peptide)	Immunochemistry	Blood, blood products
		30105 – Total calcium	Spectrophotometry	Blood, blood products
		30106 – Measured ionized calcium mesuré	Electrochemistry	Blood, blood products
		30115 - Chlorides	Electrochemistry	Blood, blood products
		30130 - CK total	Spectrophotometry	Blood, blood products
		30132 - creatinine	Spectrophotometry	Blood, blood products
		30210 - Gamma Glutamyl Transferase (GGT)	Spectrophotometry	Blood, blood products
		30212 – Blood gases analyses (pO ₂ , pCO ₂ , pH, HCO ₃ , COHb, métHb, oxyHb, SulfHb)	Selective electrode/ Spectrophotometry	Blood, blood products
		30214 – Glucose	Spectrophotometry	Blood, blood products, CSF
		30214 - Glucose	Electrochemistry	Blood, blood products
		30301 - lactate dehydrogenase (LD)	Spectrophotometry	Blood, blood products
		30332 – Total Magnesium	Spectrophotometry	Blood, blood products urine
		30362 - Osmolality	Osmometry cryoscopic	Blood, blood products urine
		30386 - Alkaline phosphatase i	Spectrophotometry	Blood, blood products
		30391 - Phosphorus	Spectrophotometry	Blood, blood products urine
		30398 - Potassium	Electrochemistry	Blood, blood products urine
30404 – Total protein (other body fluids)	Spectrophotometry	Urine, LCR		

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		30405 - Total protein (serum)	Spectrophotometry	Blood, blood products
		30412 - Protein C reactive (CRP) (includes ultrasensitive)	Immunoassay - Turbidimetry	Blood, blood products, urine
		30478 – Sodium	Electrochemistry	Blood, blood products, urine
		30513 - Troponin I or T	Immunoassay - Enzymatic (Chemiluminescence, EIA and derivatives)	Blood, blood products
		30531 - Urea	Spectrophotometry	Blood, blood products, urine
		30532 - Urine (Microscopic examination)	Visual reading	Urine
		30079 - Urine (Automated microscopic examination))	Image analysis	Urine
		30533 - Urine summary examination)	Reflectance	Urine
	01.2 Biochemistry – hormonal	30241 - Chorionic Gonadotropic Hormone (HCG) (serum or urine) (qualitative)	Immunochemistry	Urine
		30242 - Chorionic Gonadotropic Hormone (HCG) (serum) (quantitative)	Immunoassay (Chemiluminescence)	Blood, blood products
		30244 - Parathyroid hormone (PTH)	Immunoassay - Enzymatic (Chemiluminescence, EIA and derivatives)	Blood, blood products
		30516 - TSH (thyroid stimulating hormone)	Immunoassay - Enzymatic (Chemiluminescence, EIA and derivatives)	Blood, blood products
	01.4 Biochemistry – medication	30600 – Acetaminophen (Tylenol®, Temptra®)	Immunoassay - Turbidimetry	Blood, blood products
		30601 - Valproic acid (Depakene®)	Immunoassay - Turbidimetry	Blood, blood products
		30630 - Carbamazepine (Tegretol®)	Immunoassay - Turbidimetry	Blood, blood products
		30640 - Digoxin (Lanoxin®)	Immunoassay - Enzymatic (Chemiluminescence, EIA and derivatives)	Blood, blood products
		30671 -Gentamicin (Garamycine®)	Immunoassay - Turbidimetry	Blood, blood products
		30692 - Lithium (Li) (Carbolith®, Duralith®, Lithane®)	Spectrophotometry	Blood, blood products
		30731 - Phenytoin (Dilantin®)	Immunoassay - Turbidimetry	Blood, blood products
		30760 - Salicylates	Spectrophotometry	Blood, blood products
		30773 - Tobramycin (Nebcin®, Tobrex®)	Immunoassay - Turbidimetry	Blood, blood products
		30780 - Vancomycin (Vancocin®)	Immunoassay - Turbidimetry	Blood, blood products
	01.5 Biochemistry – toxicology	30177 - Ethanol (ethyl alcohol)	Spectrophotometry	Blood, blood products
	POCT	Capillary blood glucose		

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)	
		Bilirubin	Spectrophotometry / Electrochemistry	Blood, blood products	
		Qualitative HCG			
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45031 - Coronavirus (SARS-CoV-2); detection (NAAT) (approved kit) on clinical specimen	Nucleic acid detection	Clinical sample, gargling	
		45131 - Respiratory virus; multiplex detection 3 viruses (influenza A, influenza B and RSV) (NAAT) (multiplex) (approved kit) on clinical specimen	Nucleic acid detection	Clinical sample	
		45077- Meningoencephalitis; multiplex detection of 14 pathogens: 6 bacteria, 7 viruses and one yeast (NAAT) (multiplex) on cerebrospinal fluid (CSF)	Nucleic acid detection	CSF	
05.0 HEMATOLOGY	05.2 Hematology – cytology	20361 - Complete blood count (FCS) or Hb-Ht-Plaq. automated	Calculations	Blood, blood products	
			Flow cytometry	Blood, blood products	
			Fluorescence	Blood, blood products	
			Impedancemetry	Blood, blood products	
		20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	Blood, blood products	
		20380 - Leukocytes (blood) (manual)	Microscopic examination including preparation	Blood, blood products	
		20450 - Platelets (blood) (manual)		Blood, blood products	
		20321 - Cytology of liquids with cytopsin	Microscopic examination including preparation	CSF and Biological Fluids	
	20470 - Reticulocytes (automated)	Flow cytometry	Blood, blood products		
	20381 – Automated Sedimentation	Spectrophotometry	Blood, blood products		
	05.5 Hematology – hemostasis	20062 - D-Dimer (automated)	20241 - APTT Activated Partial Pain Time	Coagulometry	Blood, blood products
					Blood, blood products
			20243 - Prothrombin time (prothrombin time) (INR)		Blood, blood products
20102 – Fibrinogen (Activity)			Blood, blood products		
06.0 TRANSFUSION MEDICINE	06.0 TRANSFUSION MEDICINE	10007 - Irregular antibodies (manual identification)	Hemagglutination and derivative immunological method	Blood, blood products	
		10024 - Compatibility (manual or automated)	Hemagglutination and derivative immunological method	Blood, blood products	
		10086 - ABO-Rh blood group (manual)	Hemagglutination and derivative immunological method	Blood, blood products	

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		10028 - Coombs direct polyspecific or monospecific (automated)	Hemagglutination and derivative immunological method	Blood, blood products
		10032 - Coombs direct polyspecific or monospecific (tube technique) (manual)	Hemagglutination and derivative immunological method	Blood, blood products
		10034 - Coombs direct polyspecific or monospecific (gel technique) (manual)	Hemagglutination and derivative immunological method	Blood, blood products
		10085 – ABO-Rh blood group (automated)	Hemagglutination and derivative immunological method	Blood, blood products
		10115 – Low Rh Investigation	Hemagglutination and derivative immunological method	Blood, blood products
		10111- Irregular antibodies (automated identification)	Hemagglutination and derivative immunological method	Blood, blood products
		10134 – Common or rare erythrocyte phenotype (patient or product / by antigen / including control) (automated)	Hemagglutination and derivative immunological method	Blood, blood products
		10136 – Common erythrocyte phenotype (patient or product/ by antigen/ excluding ABO, D/ including controls) (manual)	Hemagglutination and derivative immunological method	Blood, blood products
		10150 - Irregular antibodies (manual search)	Hemagglutination and derivative immunological method	Blood, blood products
		10153 – Irregular antibodies (automated search)	Hemagglutination and derivative immunological method	Blood, blood products
	10730 - Blood group confirmation (packed red blood cells)	Hemagglutination and derivative immunological method	Blood, blood products	
07.0 MICROBIOLOGY	07.1 Microbiology – bacteriology	40022 - Helicobacter pylori (rapid urease on gastric biopsy)	Phenotypic determination: biochemical characterization	Clinical sample
	07.2 Microbiology – immunoserology	40740 - Heterophile antibody mononucleosis (agglutination)	Qualitative or quantitative agglutination	Blood, blood products
		40352 - Clostridium difficile (GDH) + (toxins A and B) (membrane ELISA) (rapid test) (feces)	Immunoassay - enzymatic (chemiluminescence, EIA and derivatives)	Faeces
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60141 - extemporaneous examination (staining included)	Microscopic examination including preparation	Fresh tissue
		60030 - Autopsy assistance (including evisceration and all samples, excluding spinal cord sample)	N/A (preanalytical)	Fresh tissue
		60100 – Cassetted with or without the assistance of the pathologist, resident or assistant pathologist	N/A (preanalytical)	Fresh tissue
		60120 - Description of placenta (cassette not included)	N/A (preanalytical)	Fresh tissue

Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
		60122 - Macroscopic description of complex surgical parts by a medical technologist (cassette not included)	N/A (preanalytical)	Fresh tissue
		60124 - Macroscopic description of non-complex surgical parts performed by a medical technologist (cassette not included)	N/A (preanalytical)	Fresh tissue
		60128 - Macroscopic description of very complex surgical parts performed by a medical technologist	N/A (preanalytical)	Fresh tissue
		60180 - Macroscopic photograph for surgery or autopsy (on file) taken by a medical technologist	N/A (preanalytical)	Fresh tissue
		60543 - Lymph node search by degreasing performed by a medical technologist.	N/A (preanalytical)	Fresh tissue
		60544 - Search for lymph nodes by palpation performed by a medical technologist.	N/A (preanalytical)	Fresh tissue
		60611 - Macroscopic description without blade, block or cassette production	N/A (preanalytical)	Fresh tissue
	08.2 Pathology – fertility	60633 - Partial spermogram (post-vasectomy)	Microscopic examination including preparation	Sperm

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

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
Publication on: 2023-05-02