

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 Montmagny)
Contact name:	Mélanie Bernard, Clinico-administrative Director
Address:	350, boulevard Taché Ouest Montmagny (Québec) G5V 3R8
Telephone:	418-338-7777, extension 54324
Website:	https://www.cisss-ca.gouv.qc.ca/accueil/
Email:	melanie.bernard@ssss.gouv.qc.ca

SCC File Number:	151110
Provider:	BNQ-EL
Provider File Number:	56729-1
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:	2021-03-26
Most Recent Accreditation:	2024-10-11
Accreditation Valid to:	2029-03-26

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 (CCN nº: 151107/BNQ nº: 56726-1)
- Centre Paul-Gilbert Centre d'hébergement de Charny, 9330, boulevard du Centre-Hospitalier, Lévis (Québec) G6X 1L6 (CCN nº: 151108/BNQ nº: 56727-1)
- Hôpital de Thetford Mines, 1717, rue Notre-Dame Est, Thetford Mines (Québec) G6G 2V4 (CCN nº: 151109/BNQ nº: 56728-1)
- Hôpital de Saint-Georges, 1515, 17e Rue, Saint-Georges (Québec) G5Y 4T8 (CCN nº: 151111/BNQ nº: 56730-1)

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

- 05.2 HEMATOLOGY CYTOLOGY
- 05.5 HEMATOLOGY HEMOSTASIS

06.0 TRANSFUSION MEDICINE

07.0 MICROBIOLOGY

- 07.2 MICROBIOLOGY IMMUNOSEROLOGY
- 07.5 MICROBIOLOGY PARASITOLOGY





SCOPE OF ACCREDITATION

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 and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30010 - Lactic acid (colorimetric)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30013 - Uric Acid	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30016 - Alanine aminotransferase (ALT)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30017 - Albumin	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30060 - Aspartate aminotransferase (AST)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30083 - Bilirubin Direct (conjugated)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30084 - Bilirubin total	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30085 - BNP (Brain Natriuretic Peptide)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30105 - Calcium total	Spectrophotometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30115 - Chloride	Electrochemistry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30130 - CK total	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30132 - Creatinine	Spectrophotometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30210 - Gamma glutamyl transferase (GGT)	Spectrophotometry	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30212 - Blood Gas (pO2, pCO2, pH, HCO3, COHb, métHb, oxyHb, SulfHb)	Selective electrode - spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30214 - Glucose	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30301 - Lactate Dehydrogenase (LD)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30332 - Total magnesium	Spectrophotometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30362 - Osmolality	Cryoscopic Osmometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30386 - Alkaline Phosphatase	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30391 - Phosphate	Spectrophotometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30398 - Potassium	Electrochemistry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30404 - Total protein (other fluids)	Spectrophotometry	Urine, CSF
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30405 - Total protein (serum)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30412 - C-reactive Protein (CRP) (including ultrasensitive)	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30478 - Sodium	Electrochemistry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30513 - Troponine T or I	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30531 - Urea	Spectrophotometry	Blood and derived products, urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30532 - Urine (microscopic exam)	Visual reading	Urine
01.0 BIOCHEMISTRY	01.1 Biochemistry – clinical	30533 - Urine (summary examination)	Reflectance	Urine





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	30241 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (qualitative)	Immunochromatography	Urine
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	30242 - Chorionic Gonadotropic Hormone (CGH) (serum or urine) (quantitative)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.2 Biochemistry – hormonal	30516 - TSH (thyrotropic hormone)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	30508 - Thyroglobulin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.3 Biochemistry – immunology	30047 - Antithyroglobulin	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30600 - Acetaminophen (Tylenol®, Tempra®)	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30601 - Valproic acid (Depakène®)	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30630 - Carbamazepine (Tegretol®)	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30640 - Digoxin (Lanoxin®)	Enzyme immunoassays (chemiluminescence, EIA and derivatives)	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30692 - Lithium (Li) (Carbolith®, Duralith®, Lithane®)	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30731 - Phenytoin (Dilantin®)	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30760 - Salicylates	Spectrophotometry	Blood and derived products
01.0 BIOCHEMISTRY	01.4 Biochemistry – medication	30780 - Vancomycine (Vancocin®)	Immunoassay - turbidimetry	Blood and derived products
01.0 BIOCHEMISTRY	01.5 Biochemistry – toxicology	30851 - Street drugs / strip / drug	Immunochromatography	Urine





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
01.0 BIOCHEMISTRY	РОСТ	Capillary blood glucose	Electrochemistry	Blood and derived products
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45033 - Coronavirus (SARS-CoV- 2); detection (NAAT) (rapid test, approved kit)	Detection of nucleic acids	Clinical sample, gargarism
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45131 - Respiratory viruses; multiplex detection of 3 viruses (influenza A, influenza B and RSV) (NAAT) (multiplex) (approved kit)	Detection of nucleic acids	Clinical sample
02.0 MOLECULAR BIOLOGY	02.3 Molecular diagnosis – infectious diseases	45077- Meningoencephalitis; multiplex detection of 14 pathogens: 6 bacteria, 7 viruses and a yeast (NAAT) (multiplex) in cerebrospinal fluid (CSF)	Detection of nucleic acids	CSF
05.0 HEMATOLOGY	05.2 Hematology – cytology	20361 - Complete blood count (CBC) or automated Hgb-HCT- Plat.	Calculation	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20361 - Complete blood count (CBC) or automated Hgb-HCT- Plat.	Flow cytometry	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20361 - Complete blood count (CBC) or automated Hgb-HCT- Plat.	Spectrophotometry	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20361 - Complete blood count (CBC) or automated Hgb-HCT- Plat.	Impedance measurement	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20362 - Differential formula (manual) (including staining)	Microscopic examination including preparation	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20321 - Fluid cytology with cytospin	Microscopic examination including preparation	CSF and biologial fluids
05.0 HEMATOLOGY	05.2 Hematology – cytology	20321 - Fluid cytology with cytospin	Flow cytometry	CSF and biologial fluids
05.0 HEMATOLOGY	05.2 Hematology – cytology	20321 - Fluid cytology with cytospin	Impedance measurement	CSF and biologial fluids
05.0 HEMATOLOGY	05.2 Hematology – cytology	20380 - Leukocytes (blood) (manual)	Microscopic examination including preparation	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20450 - Platelets (blood) (manual)		Blood and derived products



Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
05.0 HEMATOLOGY	05.2 Hematology – cytology	20470 - Reticulocytes (automated)	Flow cytometry	Blood and derived products
05.0 HEMATOLOGY	05.2 Hematology – cytology	20381 - Automated sedimentation	Spectrophotometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	20062 - D-Dimer (automated)	Turbidimetry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	20102 - Fibrinogen (activity)	Coagulometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	20241 - Partial thromboplastin time (PTT)	Coagulometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	20243 - Prothrombin time (INR) including fibrinogen derivative	Coagulometry	Blood and derived products
05.0 HEMATOLOGY	05.5 Hematology – hemostasis	20130 - Anti-Xa Heparin	Spectrophotometry	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10007 - Irregular antibodies (manual identification)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10024 - Compatibility (manual or automated)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10028 - Coombs direct polyspecific or monospecific (automated)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10034 - Polyspecific or monospecific direct coombs (gel technique) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10045 – Thawing of blood product or breast milk	N/A	N/A
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10085 - ABO-Rh blood group (automated)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10086 - ABO-Rh blood type (manual)	Immunological method of hemagglutination and derivative	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10111 - Irregular antibodies (automated identification)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10115 - Weak Rh Investigation	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10133 – Pooling of labile blood products	N/A	N/A
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10134 - Common or rare erythrocyte phenotype (patient or product/by antigen/including control) (automated)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10136 - Common Red Blood Cell Phenotype (patient or product/by antigen/excluding ABO, D/(including controls) (manual)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10150 - Irregular antibodies (manual search)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10152 – Reconstitution of stable blood product (e.g. coagulation factor, immunoglobulin etc.)	N/A	N/A
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10153 - Irregular antibodies (automated search)	Immunological method of hemagglutination and derivative	Blood and derived products
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10179 - Syringe of labile blood product	N/A	N/A
06.0 TRANSFUSION MEDICINE	06.0 Transfusion medicine	10730 - Blood group confirmation (red blood cells)	Immunological method of hemagglutination and derivative	Blood and derived products
07.0 MICROBIOLOGY	07.2 Microbiology – immunoserology	40740 - Mononucleosis heterophilic antibody (agglutination)	Qualitative or quantitative agglutination	Blood and derived products





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
07.0 MICROBIOLOGY	07.5 Microbiology – parasitology	41120 - Malaria (rapid detection of Ag) (Immunochromatography)	Immunochromatography	N/A
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60141 - Extemporaneous examination (including staining)	Microscopic examination including preparation	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60030 - Autopsy assistance (including evisceration and all sampling, excluding spinal cord sampling)	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60100 - Cassette setting with or without assistance to pathologist, resident or assistant pathologist	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60120 - Description of placenta (cassetting not included)	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60122 - Macroscopic description of complex surgical specimens by a medical technologist (cassetting not included)	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60124 - Macroscopic description of non-complex surgical specimens by a medical technologist (cassette setting not included)	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60128-Macroscopic description of highly complex surgical specimens by a medical technologist or pathologist's assistant (cassette setting not included)	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60180 - Macroscopic photograph for surgery or autopsy (on file) by medical technologist	N/A (preanalytical)	Fresh tissue





Discipline	Sub-discipline	Nature of the test	Analytical principle	Matrix (sample)
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60543 - Node finding by degreasing performed by medical technologist	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60544 - Palpation of lymph nodes by a medical technologist	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.1 Pathology – clinical	60611 - Macroscopic description without production of slide, block or cassette	N/A (preanalytical)	Fresh tissue
08.0 ANATOMICAL PATHOLOGY	08.2 Pathology – fertility	60633 - Partial spermogram (post-vasectomy)	Microscopic examination including preparation	Semen

<u>Notes</u>

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: 2024-10-11





APPENDIX A

SITES UNDER THE RESPONSIBILITY OF THE ACCREDITED LABORATORY

Département clinique de médecine de laboratoire de l'HÔTEL-DIEU DE LÉVIS (site Hôpital de Montmagny) 350, boulevard Taché Ouest Montmagny (Québec) G5V 3R8

Sites	Address	Capillary blood glucose	Test 2	Test 3	Test 4
CLSC St-Jean- Port-Joli	430 Rue Jean- Leclerc, Saint- Jean-Port-Joli, QC G0R 3G0	Х			
CHSLD St-Jean- Port-Joli	430 Rue Jean- Leclerc, Saint- Jean-Port-Joli, QC G0R 3G0	Х			
CHSLD St- Eugène	60 Chemin Lamartine O, L'Islet, QC G0R 2B0	Х			
CLSC St-Fabien	10 Rue Alphonse, Saint-Fabien- de-Panet, QC G0R 2J0	Х			
CHSLD St- Fabien	19 Rue Principale E, Saint-Fabien- de-Panet, QC G0R 2J0	Х			
CHSLD Cap St- Ignace	146 Rue du Manoir E, Cap- Saint-Ignace, QC G0R 1H0	Х			
CLSC Montmagny	168 Rue Saint Joseph, Montmagny, QC G5V 1H8	Х			
CLSC Île aux Grues	101, chemin de la Volière, Saint-Antoine- de-l'Isle-aux- Grues, QC G0R 1P0	Х			
CLSC St- Pamphile	103 Rue du Foyer N, Saint- Pamphile, QC G0R 3X0	Х			

