

MEDICAL LABORATORY ACCREDITATION PROGRAM

Scope of Accreditation

Legal Name of Accredited Laboratory: Département de médecine de laboratoire du CHU de Québec – Université Laval (site INSTITUT UNIVERSITAIRE DE CARDIOLOGIE ET DE PNEUMOLOGIE DE QUÉBEC)

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|-----------------------------------|--|
| SCC File Number: | 151155 |
| Provider: | BNQ-EL |
| Provider File Number: | 56445-1 |
| 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.

- Centre hospitalier de l'Université Laval, 2705, boul. Laurier, Québec (Québec) G1V 4G2 (No CCN : 151142 / No BNQ : 56432-1),
- 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^e Rue, Québec (Québec) G1J 1Z4 (No CCN : 151154 / No BNQ : 56444-1),

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

02.0 MOLECULAR BIOLOGY*

- 02.2 MOLECULAR DIAGNOSIS – HEMATOLOGY
- 02.5 MOLECULAR DIAGNOSIS – ONCOLOGY

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

05.0 HEMATOLOGY*

- 05.2 HEMATOLOGY – CYTOLOGY
- 05.3 HEMATOLOGY – ERYTHROCYTIC
- 05.5 HEMATOLOGY – HEMOSTASIS
- 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
- 07.3 MICROBIOLOGY – MYCOBACTERIOLOGY
- 07.4 MICROBIOLOGY – MYCOLOGY

08.0 ANATOMICAL PATHOLOGY

- 08.1 PATHOLOGY – CLINICAL
- 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 | Reflectance | Urine |
| | | | Refractometry | Urine |
| | | Osmolality measurement | Cryoscopic Osmometry | Blood and derived products, urine |
| | | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | Calculation | Blood and derived products, urine, other biological fluids |
| | | | Co-Oxymetry | Blood and derived products, other biological fluids |
| | | | Electrochemistry | Blood and derived products, CSF, urine, other biological fluids |
| | | | Microscopic examination including preparation | Urine, other biological fluids |
| | | | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Blood and derived products |
| | | | Immunoassay - Nephelometry | Blood and derived products |
| | | | Visual reading | Blood and derived products, other biological fluids, urine |
| | | | Enzymatic method | Blood and blood products, urine, CSF, other biological fluids |
| | | | Nephelometry | Urine, other biological fluids |
| | | | Reflectance | Urine |
| | Spectrophotometry | Blood and derived products, CSF, urine, other biological fluids | | |
| | 01.2 Biochemistry – hormonal | | Immunoassay - Nephelometry | Blood and derived products, urine |
| | | | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | 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 - Nephelometry | Blood and derived products |
| | | | Spectrophotometry | Blood and derived products |
| | 01.5 Biochemistry – toxicology | Research, identification and/or determination of the concentration of toxic substances or analytes | Fluorometry | Blood and derived products |
| Visual reading - Immunoassay | | | Urine | |
| Spectrophotometry | | | Blood and derived products | |
| POCT | | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | Blood gases and electrolytes Blood sugar | Blood and derived products |

| Discipline | Sub-discipline | Nature of the test | Analytical principle | Matrix (sample) |
|---------------------------|--|--|---|--|
| 02.0 MOLECULAR BIOLOGY | 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 sample, stool |
| | 02.5 Molecular Diagnosis Oncology | Characterization and/or quantification of molecular anomalies: detection of mutations, inversions, translocations, methylations, deletions | Molecular in situ hybridization (CISH, FISH) | Tissue/cell blocks (paraffin) |
| | | | Detection of nucleic acids Nucleic Acid Amplification Tests (NAATs) | Tissue/cell blocks (paraffin) |
| | | Research for point mutations, short insertions/deletions, fusions and oncogenic isoforms by next generation sequencing | Next-Generation Sequencing (NGS) | Tissue/cell blocks (paraffin) |
| | POCT | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | SARS-CoV-2 | Clinical sample |
| 05.0 HEMATOLOGY | 05.2 Hematology – cytology | Hemogram, research, identification and/or cells quantification | Flow cytometry | Blood and derived products |
| | | | Microscopic examination including preparation | Blood and derived products, CSF, other biological fluids |
| | | | Impedance measurement | Blood and derived products |
| | | Red blood cell aggregation technique | Precipitation | Blood and derived products |
| | 05.3 Hematology – erythrocytic | Research and determination of hemoglobin concentration | Calculation | Blood and derived products |
| | | | Spectrophotometry | Blood and derived products |
| | 05.5 Hematology – hemostasis | Determination of hemostasis parameters | Coagulometry | Blood and derived products |
| | | | Chromogenic method | Blood and derived products |
| | | | Chronometric method | Blood and derived products |
| | | | Turbidimetry | Blood and derived products |
| | | Bleeding time | Aggregometry | Blood and derived products |
| | 05.7 Hematology – immunology | Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Blood and derived products |
| | | | Chromogenic method | Blood and derived products |
| Spectrophotometry | | | Blood and derived products | |
| | POCT | 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 | 06.0 Transfusion medicine | Research and determination of erythrocyte antigens; determination of blood groups | Immunological method of hemagglutination and derivative | Blood and derived products |
| 07.0 MICROBIOLOGY | 07.1 Microbiology – bacteriology | Characterization of the sensitivity of bacteria to different substances | Phenotypic determination: sensitivity tests | Isolate |

| Discipline | Sub-discipline | Nature of the test | Analytical principle | Matrix (sample) |
|---------------------------|--------------------------------------|--|--|--|
| | | Preparation for bacterial research and identification | Cell culture | Blood and derived products, CSF, urine, secretions, clinical sample |
| | | | Microscopic examination including preparation | Blood and derived products, secretions, clinical sample, other biological fluids |
| | | Research and identification of bacteria, mycobacteria, yeasts and fungi | Microscopic examination including preparation | Isolate |
| | | Research and identification of toxins, enzymes, antibodies and bacterial antigens | Phenotypic determination: biochemical characterization | Isolate |
| | | | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Urine |
| | 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 |
| | 07.3 Microbiology – mycobacteriology | Research and identification of mycobacteria | Mycobacterial culture | Blood and blood products, clinical sample |
| | | | Microscopic examination including preparation | Clinical sample |
| | 07.4 Microbiology – mycology | Research and identification of fungi and yeast | Fungal culture | Clinical sample |
| | | | Microscopic examination including preparation | Clinical sample, isolate |
| | | | 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 | Blood and derived products, CSF |
| 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 |
| | | | Immunohistochemistry | Tissue/cell blocks (paraffin, others), cells |
| | 08.3 Pathology – cytology | Morphological observation of cellular constituents | Microscopic examination including preparation | 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 www.scc.ca.

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Publication on: 2024-10-10