

## MEDICAL LABORATORY ACCREDITATION PROGRAM

### Scope of Accreditation

**Legal Name of Accredited Laboratory:** Département clinique de médecine de laboratoire du Centre hospitalier de l'Université de Montréal (CHUM) (Site Hôpital Maisonneuve-Rosemont)

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|                                   |  |
|-----------------------------------|--|
| <b>SCC File Number:</b>           | 151128   |
| <b>Provider:</b>                  | BNQ-EL   |
| <b>Provider File Number:</b>      | 56657-1  |
| <b>Accreditation Standard(s):</b> | ISO 15189:2012 Medical laboratories – Requirements for quality and competence<br>ISO 22870:2016 Point of care testing (POCT) – Requirements for quality and competence<br>CAN/CSA-Z902-20 Blood and blood components |
| <b>Program Specialty Area:</b>    | Medical  |
| <b>Initial Accreditation:</b>     | 2021-03-25   |
| <b>Most Recent Accreditation:</b> | 2023-11-16   |
| <b>Accreditation Valid to:</b>    | 2025-03-25   |

*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 de Montréal, 1051, Sanguinet St., Montréal (Québec) H2X 3E4 (CCN no.: 151126 / BNQ no.: 56655-1)
- Hôpital Santa Cabrini, 5655, Saint-Zotique E. St., Montréal (Québec) H1T 1P7 (CCN no.: 151129 / BNQ no.: 56658-1)
- Hôpital de Verdun, 4000, Lasalle Blvd., Montréal (Québec) H4G 2A3 (CCN no.: 151132 / BNQ no.: 56661-1)
- Hôpital Notre-Dame, 1560, Sherbrooke E. St., Montréal (Québec) H2L 4M1 (CCN no.: 151133 / BNQ no.: 56662-1)
- Hôpital du Sacré-Cœur de Montréal, 5400, Gouin W. Blvd., Montréal (Québec) H4J 1C5 (CCN no.: 151134 / BNQ no.: 56663-1)
- Hôpital Fleury, 2180, Fleury E. St., Montréal (Québec) H2B 1K3 (CCN no.: 151135 / BNQ no.: 56664-1)
- Hôpital Jean-Talon, 1385, Jean-Talon E. St., Montréal (Québec) H2E 1S6 (CCN no.: 151136 / BNQ no.: 56665-1)
- Institut de cardiologie de Montréal, 5000, Bélanger St., Montréal (Québec) H1T 1C8 (CCN no.: 151138 / BNQ no. : 56667-1)

## 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
- 02.5 MOLECULAR DIAGNOSIS – ONCOLOGY

### 04.0 GENETICS / CYTOGENETICS

- 04.2 GENETICS – CYTOGENETICS

## SCOPE OF ACCREDITATION

### 05.0 HEMATOLOGY

- 05.1 HEMATOLOGY – CYTOCHEMISTRY
- 05.2 HEMATOLOGY – CYTOLOGY
- 05.3 HEMATOLOGY – ERYTHROCYTIC
- 05.4 HEMATOLOGY – GRAFTS
- 05.5 HEMATOLOGY – HEMOSTASIS
- 05.6 HEMATOLOGY – IMMUNOCYTOMETRY
- 05.7 HEMATOLOGY – IMMUNOLOGY

### 06.0 TRANSFUSION MEDICINE

### 07.0 MICROBIOLOGY

- 07.1 MICROBIOLOGY – BACTERIOLOGY
- 07.2 MICROBIOLOGY – IMMUNOSEROLOGY
- 07.3 MICROBIOLOGY – MYCOBACTERIOLOGY
- 07.4 MICROBIOLOGY – MYCOLOGY
- 07.5 MICROBIOLOGY – PARASITOLOGY

### 08.0 ANATOMICAL PATHOLOGY

- 08.1 PATHOLOGY – CLINICAL
- 08.2 PATHOLOGY – FERTILITY
- 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, other biological fluids  |
|                   |                              | Osmolality measurement  | Cryoscopic Osmometry   | Blood and derived products, feces, urine, other biological fluids         |
|                   |                              | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | Electrochemistry       | CSF, blood and derived products, feces, urine and other biological fluids |
|                   |                              |   | Chromatography         | Blood and derived products, feces, urine, secretions                      |
|                   |                              |   | Radial immunodiffusion | Blood and blood products, feces, urine                                    |
|                   |                              |   | Co-oximetry            | Blood and derived products  |

| Discipline               | Sub-discipline                 | Nature of the test  | Analytical principle   | Matrix (sample)  |
|--------------------------|--------------------------------|---|--|--|
|                          |                                |   | Electrophoresis  | CSF, blood and derived products, urine                                 |
|                          |                                |   | Microscopic examination including preparation  | Other biological fluids, blood and derived products, feces, urine      |
|                          |                                |   | Automated imaging microscopy   | Urine  |
|                          |                                |   | Enzyme immunoassays (chemiluminescence, EIA and derivatives)   | CSF, blood and derived products, urine, feces, other biological fluids |
|                          |                                |   | Immunoassay - turbidimetry   | Blood and derived products, urine                                      |
|                          |                                |   | Visual reading   | Feces  |
|                          |                                |   | Immunoassay - fluorescence   | Blood and derived products   |
|                          |                                |   | Spectrophotometry  | Blood and derived products, feces, urine, CSF, other biological fluids |
|                          | 01.2 Biochemistry – hormonal   | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | Chromatography   | Blood and derived products, urine                                      |
|                          |                                |   | Enzyme immunoassays (chemiluminescence, EIA and derivatives)   | Blood and derived products, urine, CSF, other biological fluids        |
|                          |                                |   | Mass spectroscopy  | Blood and derived products, urine                                      |
|                          | 01.3 Biochemistry – immunology | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | Qualitative or quantitative agglutination  | Blood and derived products   |
|                          |                                |   | Enzyme immunoassays (chemiluminescence, EIA and derivatives)   | Blood and derived products, other biological fluids                    |
|                          |                                |   | Immunoassay - fluorescence   | 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   |
|                          |                                |   | Mass spectroscopy  | 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              | Enzyme immunoassays (chemiluminescence, EIA and derivatives)   | Blood and derived products, urine, CSF, other biological fluids        |
|                          |                                |   | Spectrophotometry  | CSF, blood and derived products, urine                                 |
|                          | POCT                           | Research, identification and concentration determination of organic and inorganic molecules and enzyme activity | Blood gas analysis with or without co-oximetry (pO <sub>2</sub> , pCO <sub>2</sub> , pH, HCO <sub>3</sub> , COHb, meHb, oxyHb, SulfHb, total CO <sub>2</sub> ) | Blood and derived products, urine, secretions                          |
|                          |                                |   | Summary examination (urine) (visual reading)   |  |
|                          |                                |   | Transcutaneous assessment of bilirubin levels  |  |
|                          |                                |   | Determination of activated partial thromboplastin time (ACT)   |  |
|                          |                                |   | White blood cell count and neutrophil percentage   |  |
|                          |                                |   | Screening for SARS-CoV-2   |  |
|                          |                                |   | Detection of group A streptococcus   |  |
|                          |                                |   | Capillary glucose assay  |  |
| Hemoglobin determination |                                |   |  |  |

| Discipline                           | Sub-discipline                                 | Nature of the test   | Analytical principle                              | Matrix (sample)   |
|--------------------------------------|--|--|---|---|
|                                      |  |  | Urine density measurement                         |   |
|                                      |  |  | Detection of chorionic gonadotropin hormone (HCG) |   |
|                                      |  |  | Amniotic membrane rupture test                    |   |
| 02.0 MOLECULAR BIOLOGY               | 02.2 Molecular diagnosis – hematology          | Genotyping and cell typing (erythrocytes, platelets, granulocytes, etc.)   | Detection of nucleic acids                        | DNA or RNA clinical sample, blood and derived products, marrow  |
|                                      |  |  | Conventional sequencing                           | DNA or RNA clinical sample, blood and derived products, marrow  |
|                                      | 02.3 Molecular diagnosis – infectious diseases | Research and identification and/or concentration determination (quantification) of viral, bacterial, fungal and parasitic nucleic acids          | Detection of nucleic acids                        | CSF, blood and derived products, fresh tissue, clinical specimen, urine, feces, secretions, other biological fluids |
|                                      | 02.4 Molecular diagnosis – hereditary diseases | Characterization and/or quantification of molecular anomalies  | Detection of nucleic acids                        | DNA or RNA clinical sample, cells, blood and derived products, other biological fluids, marrow                      |
|                                      | 02.5 Molecular diagnosis – oncology            | Characterization and/or quantification of molecular anomalies: detection of mutations, inversions, translocations, methylations, deletions, etc. | Detection of nucleic acids                        | DNA or RNA clinical sample, tissue/cell blocks (kerosene wax, other), fresh tissue, cells                           |
|                                      |  |  | Molecular in situ hybridization (CISH, FISH)      | Tissue/cell blocks (kerosene wax, other), cells and fresh tissue  |
|                                      |  |  | Next generation sequencing                        | Tissue/cell blocks (kerosene wax, others), fresh tissue, cells, clinical sample DNA or RNA                          |
|                                      |  |  | Conventional sequencing                           | Tissue/cell blocks (kerosene wax, other), fresh tissue, cells, DNA or RNA from clinical samples,                    |
| 04.0 GENETICS - CYTOGENETICS         | 04.2 Genetics – cytogenetics                   | Karyotype - Numerical and morphological study of chromosomes   | Microscopic examination including preparation     | Marrow, blood and derived products, fresh tissue  |
|                                      |  | Search for chromosomal and/or molecular abnormalities  | Molecular in situ hybridization (CISH, FISH)      | Blood and derived products, cells, marrow   |
|                                      |  |  | Microscopic examination including preparation     | Blood and derived products, cells, marrow   |
| 05.0 HEMATOLOGY                      | 05.1 Hematology – cytochemistry                | Determination of hematocytochemistry parameters  | Microscopic examination including preparation     | Cells, marrow, blood and derived products   |
|                                      |  | Hemogram, research, identification and/or cells quantification   | Microscopic examination including preparation     | Cells, marrow, blood and derived products   |
|                                      | 05.2 Hematology – cytology                     | Hemogram, research, identification and/or cells quantification   | Flow cytometry                                    | Marrow, blood and derived products, other biological fluids, CSF  |
|                                      |  |  | Microscopic examination including preparation     | Cells, marrow, blood and derived products, urine, other biological fluids, CSF                                      |
|                                      |  |  | Spectrophotometry                                 | Blood and derived products  |
|                                      |  |  | Calculation                                       | Blood and derived products  |
|                                      |  |  | Impedance measurement                             | Blood and derived products  |
| Red blood cell aggregation technique | Precipitation                                  | Blood and derived products   |   |   |

| Discipline   | Sub-discipline   | Nature of the test   | Analytical principle   | Matrix (sample)  |
|--|--|--|--|--|
|  | 05.3 Hematology – erythrocytic   | Detection and quantification of markers/glycoproteins/enzymes  | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Blood and derived products   |
|  |  | Search for cellular abnormalities  | Microscopic examination including preparation                | Blood and derived products, urine, other biological fluids, marrow |
|  |  |  | Visual reading   | Blood and derived products   |
|  |  |  | Macroscopic examination                                      | Other biological fluids, CSF                                       |
|  |  | Research and determination of hemoglobin concentration   | Electrophoresis  | Blood and derived products   |
|  |  |  | Spectrophotometry  | Blood and derived products   |
|  | 05.4 Hematology – graft  | HLA genotyping, chimerism, genetic polymorphisms   | Detection of nucleic acids                                   | DNA or RNA clinical samples, blood and derived products            |
|  |  |  | Next generation sequencing                                   | DNA or RNA clinical samples, blood and derived products            |
|  |  |  | Conventional sequencing                                      | DNA or RNA clinical samples, blood and derived products            |
|  |  | Identification and/or concentration determination of antibodies and other protein compounds                | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Blood and derived products   |
|  | Hematocytological phenotyping  | Molecular in situ hybridization (CISH, FISH)   | Bone marrow, blood and derived products                      |  |
|  | 05.5 Hematology – hemostasis   | Determination of hemostasis parameters   | Coagulometry   | Blood and derived products   |
|  |  |  | Immunoassay - turbidimetry                                   | Blood and derived products   |
|  |  |  | Chromogenic method   | Blood and derived products   |
|  |  |  | Modified radial immunodiffusion                              | Blood and derived products   |
|  |  |  | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Blood and derived products   |
|  |  |  | Visual reading   | Blood and derived products   |
|  |  |  | Precipitation  | Blood and derived products   |
|  |  | Fibrinolysis investigation   | Visual reading   | Blood and derived products   |
|  | Platelet tests, search for and determination of heparin-dependent antibody concentration | Aggregometry   | Blood and derived products                                   |  |
|  | 05.6 Hematology – immunocytometry  | Hematocytological phenotyping  | Flow cytometry   | Marrow, blood and derived products, other biological fluids, CSF   |
|  | 05.7 Hematology – immunology   | Search for cellular abnormalities  | Precipitation  | Blood and derived products   |
|  |  | Research, identification and/or determination of the concentration of proteins, anticoagulants, antibodies | Immunoassay - turbidimetry                                   | Blood and derived products   |
| Immunoassay - fluorescence                                   |  |  | Blood and derived products                                   |  |
| Enzyme immunoassays (chemiluminescence, EIA and derivatives) |  |  | Blood and derived products                                   |  |
| 06.0 TRANSFUSION MEDICINE                                    | 06.0 Transfusion medicine  | Comparative test   | Immunological method of hemagglutination and derivative      | Blood and derived products   |
|  |  | Research and determination of erythrocyte antigens; determination of blood groups                          | Immunological method of hemagglutination and derivative      | Blood and derived products   |
|  |  | Research and/or identification of anti-erythrocytic antibodies   | Immunological method of hemagglutination and derivative      | Blood and derived products   |

| Discipline        | Sub-discipline                   | Nature of the test   | Analytical principle   | Matrix (sample)  |  |
|-------------------|----------------------------------|--|--|--|--|
| 07.0 MICROBIOLOGY | 07.1 Microbiology – bacteriology | Characterization of the sensitivity of bacteria to different substances  | Phenotypic determination: sensitivity tests                  | Isolate  |  |
|                   |                                  | Preparation for bacterial research and identification  | Bacterial culture  | Clinical specimen, other biological fluids, feces, urine, CSF, fresh tissue, blood and derived products, secretions            |  |
|                   |                                  |  | Microscopic examination including preparation                | Clinical specimen, other biological fluids, feces, urine, CSF, fresh tissue, blood and derived products, secretions            |  |
|                   |                                  | Research and identification of nucleic acids, toxins, enzymes, antibodies and bacterial antigens                               | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Feces, urine, fresh tissue, CSF, other biological fluids, blood and derived products   |  |
|                   |                                  | Research and identification of bacteria  | Microscopic examination including preparation                | Other biological fluids, feces, urine, CSF, fresh tissue, blood and derived products, secretions, isolate, clinical sample     |  |
|                   |                                  |  | Chromogenic method   | Other biological fluids, feces, urine, CSF, fresh tissue, blood and derived products, secretions, isolate, clinical sample     |  |
|                   |                                  |  | Phenotypic determination by mass spectrometry                | Isolate  |  |
|                   |                                  |  | 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  |
|                   |                                  | 07.3 Microbiology – mycobacteriology   | Diagnosis of latent tuberculosis infection                   | Enzyme immunoassays (chemiluminescence, EIA and derivatives)   | Blood and derived products   |
|                   | Enzyme-linked immunoassay (IGRA) |  |  |  |  |
|                   | 07.4 Microbiology – mycology     | Research and identification of mycobacteria  | Microscopic examination including preparation                | Clinical specimen, blood and derived products, fresh tissue, other biological fluids, urine, CSF, secretions                   |  |
|                   |                                  |  | Mycobacterial culture  |  |  |
|                   |                                  | Characterizing the sensitivity of infectious agents to different substances  | Phenotypic determination: sensitivity tests                  | Isolate  |  |
|                   |                                  |  | Research and identification of fungi and yeast               | Microscopic examination including preparation  | Blood and derived products, clinical sample, fresh tissue, isolate, other biological fluids, feces, urine, CSF, secretions |
|                   |                                  |  |  | Fungal culture   |  |
|                   |                                  |  |  | Chromogenic method   |  |
|                   |                                  |  | Immunoassay - fluorescence                                   | Clinical sample, isolate, other biological fluids, secretions  |  |
|                   |                                  |  | Phenotypic determination: biochemical characterization       | Isolate  |  |
|                   |                                  | Phenotypic determination by mass spectrometry  | Isolate  |  |  |
|                   |                                  | Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents | Enzyme immunoassays (chemiluminescence, EIA and derivatives) | Clinical samples, other biological fluids, CSF, blood and derived products   |  |
|                   | Immunochemistry                  |  | CSF, blood and derived products                              |  |  |
|                   | 07.5 Microbiology – parasitology | Research and identification of parasites   | Microscopic or macroscopic examination including preparation | Blood and derived products, feces, tissue and other  |  |

| Discipline                | Sub-discipline             | Nature of the test   | Analytical principle   | Matrix (sample)  |
|---------------------------|----------------------------|--|--|--|
|                           |                            |  | Parasite culture   | biological fluids, secretions, clinical sample   |
|                           |                            | Research, identification and/or determination of the concentration of antibodies and/or antigens specific to infectious agents                               | Immunochromatography   | Blood and derived products   |
| 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 | Macroscopic examination including preparation                              | Fresh tissue   |
|                           |                            |  | Microscopic examination including preparation                              | Fresh tissue, tissue/cell blocks (kerosene wax, other), cells  |
|                           |                            | Immunohistochemistry   | Fresh tissue, tissue/cell blocks (kerosene wax, other) kerosene wax, cells |  |
|                           |                            | Macroscopic examination including preparation  | Fresh tissue   |  |
|                           |                            | Evaluation of the proportion of specific constituents/antigens/enzymes   | Immunoassay - fluorescence   | Fresh tissue, tissue/cell blocks (kerosene wax, other) kerosene wax, cells                                   |
|                           | 08.2 Pathology – fertility | Morphological study and cell identification  | Microscopic examination including preparation                              | Semen  |
|                           | 08.3 Pathology – cytology  | Morphological observation of cellular constituents   | Microscopic examination including preparation                              | Secretions, clinical sample cells, urine, other biological fluids, tissue blocks (kerosene wax, others), CSF |

### 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](http://www.scc.ca).

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