

MEDICAL LABORATORY ACCREDITATION PROGRAM

Scope of Accreditation

| Legal Name of Accredited Laboratory: | Biron Laboratoire Médical Inc. |
|--------------------------------------|---|
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| SCC File Number: | 151281 |
|----------------------------|---|
| Provider: | BNQ-EL |
| Provider File Number: | 61454-1 |
| Accreditation Standard(s): | ISO 15189:2012 Medical laboratories – Requirements for quality and competence |
| Program Specialty Area: | Medical |
| Initial Accreditation: | 2022-10-10 |
| Most Recent Accreditation: | 2024-06-07 |
| Accreditation Valid to: | 2026-10-10 |

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.

 Biron Laboratoire Médical Inc., 800, Square Victoria, suite 2700, Montréal (Québec) H4Z 1C3 (CCN No.: 151321/BNQ No.: 66223-1)

SCOPE OF ACCREDITATION

01.0 **BIOCHEMISTRY**

- 01.1 BIOCHEMISTRY CLINICAL
- 01.2 BIOCHEMISTRY HORMONAL
- 01.3 BIOCHEMISTRY IMMUNOLOGY
- 01.5 BIOCHEMISTRY TOXICOLOGY

02.0 MOLECULAR BIOLOGY

- 02.1 PHARMACOGENETIC
- 02.3 MOLECULAR DIAGNOSIS INFECTIOUS DISEASES

05.0 HEMATOLOGY

- 05.2 HEMATOLOGY CYTOLOGY
- 05.3 HEMATOLOGY ERYTHROCYTIC
- 05.5 HEMATOLOGY HEMOSTASIS
- 05.7 HEMATOLOGY IMMUNOLOGY

07.0 MICROBIOLOGY

- 07.1 MICROBIOLOGY BACTERIOLOGY
- 07.2 MICROBIOLOGY IMMUNOSEROLOGY
- 07.5 MICROBIOLOGY PARASITOLOGY
- 07.6 MICROBIOLOGY VIROLOGY

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 | Microscopic examination including preparation | Urine |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and | Spectrophotometry | Blood, blood products and urine |





| Discipline | Sub-discipline | Nature of the test | Analytical principle | Matrix (sample) |
|-------------------|-----------------------------------|--|---|---------------------------------------|
| | | inorganic molecules and enzymatic activity | | |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Enzymatic immunoassays (chimiluminescence, EIA and derivatives) | Blood, blood products urine and feces |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Refractometry | Urine |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Turbidimetric-immunoassay | Blood, blood products urine and feces |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Potentiometry | Blood, blood products and urine |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Electrophoresis | Blood and blood products |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Electrophoresis - Immunofixation | Blood and blood products |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Turbidimetry | Urine |
| 01.0 BIOCHEMISTRY | 01.1 Biochemistry – clinical | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Spectrophotometry | Blood and blood products |
| 01.0 BIOCHEMISTRY | 01.2 Biochemistry – hormonal | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Enzymatic immunoassay (chimiluminescence, EIA et derivatives) | Blood and blood products |
| 01.0 BIOCHEMISTRY | 01.2 Biochemistry – hormonal | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Immunochromatography | Urine |
| 01.0 BIOCHEMISTRY | 01.3 Biochemistry – immunology | Detection, identification, and/or determination of the concentration of organic and | Qualitative or quantitative agglutination | Blood and blood products |





| Discipline | Sub-discipline | Nature of the test | Analytical principle | Matrix (sample) |
|------------------------|---|--|---|---|
| | | inorganic molecules and enzymatic activity | | |
| 01.0 BIOCHEMISTRY | 01.3 Biochemistry – immunology | Detection, identification, and/or determination of the concentration of organic and inorganic molecules and enzymatic activity | Enzymatic immunoassay (chimiluminescence, EIA et derivatives) | Blood and blood products |
| 01.0 BIOCHEMISTRY | 01.5 Biochemistry – toxicology | Detection, identification and/or determination of the concentration of the toxic analyte or substance | Spectrophotometry | Urine |
| 01.0 BIOCHEMISTRY | 01.5 Biochemistry – toxicology | Detection, identification and/or determination of the concentration of the toxic analyte or substance | Enzymatic immunoassay (EMIT, CEDIA) | Urine |
| 02.0 MOLECULAR BIOLOGY | 02.1 Pharmacogenetic | Detection for genetic markers influencing medication response | Genotyping by primer extension | Secretions |
| 02.0 MOLECULAR BIOLOGY | 02.3 Molecular diagnosis – infectious diseases | Detection, identification and/or determination of the quantitative concentration of viral, bacterial, or fungal nucleic acids | Nucleic acid detection | Urine, feces, secretions and clinical samples |
| 05.0 HÉMATOLOGY | 05.2 Hematology – cytology | Hemogram, detection, identification and/or cell count | Microscopic examination including preparation | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.2 Hematology – cytology | Hemogram, detection, identification and/or cell count | Flow cytometry - impedancemetry - fluorescence - Calculation - Spectrophotometry | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.2 Hematology – cytology | Hemogram, detection, identification and/or cell count | Flow cytometry | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.3 Hematology - erythrocytic | RBC aggregation | Precipitation / Photometry | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.5 Hematology – hemostasis | Determination of hemostasis parameters | Immunoassay-fluorescence | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.5 Hematology – hemostasis | Determination of hemostasis parameters | Chronogenic | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.5 Hematology – hemostasis | Detection and identification of nucleic acids, toxins, enzymes, bacterial antibodies, and antigens | Chronogenic | Blood and blood products |
| 05.0 HÉMATOLOGY | 05.7 Hematology – immunology | Detection, identification and/or determination of concentration of proteins, anticoagulants, antibodies | Immunoassay fluorescence | Blood and blood products |
| 07.0 MICROBIOLOGY | 07.1 Microbiology – bacteriology | Preparation for detection and identification of bacteria | Bacterial culture | Sperm, urine, feces, and secretions |
| 07.0 MICROBIOLOGY | 07.1 Microbiology – bacteriology | Detection and identification of bacterial nucleic acids, toxins, enzymes antibodies and antigens | Immunochromatography | Feces |





| Discipline | Sub-discipline | Nature of the test | Analytical principle | Matrix (sample) |
|-------------------|---------------------------------------|--|--|---|
| 07.0 MICROBIOLOGY | 07.1 Microbiology – bacteriology | Detection, identification and/or determination of antibody or antigen concentrations for infectious agents | Immunochromatography | Secretions |
| 07.0 MICROBIOLOGY | 07.2 Microbiology – immunoserology | Detection, identification and/or determination of antibody or antigen concentrations for infectious agents | Qualitative or quantitative agglutination | Blood and blood products |
| 07.0 MICROBIOLOGY | 07.2 Microbiology – immunoserology | Detection, identification and/or determination of antibody or antigen concentrations for infectious agents | Enzymatic immunoassay- (chimiluminescence, EIA et derivatives) | Blood and blood products |
| 07.0 MICROBIOLOGY | 07.5 Microbiology – parasitology | Hemogram, search, identification and or cell count | Microscopic examination including preparation | Blood and blood products |
| 07.0 MICROBIOLOGY | 07.5 Microbiology – parasitology | Detection and identification of parasites | Microscopic examination including preparation | Blood and blood products, feces, secretions |
| 07.0 MICROBIOLOGY | 07.6 Microbiology – virology | Detection, identification and/or determination of antibody or antigen concentrations for infectious agents | Immunoassay-fluorescence | Secretions |

<u>Notes</u>

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 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: 2024-06-10

