

## MEDICAL LABORATORY ACCREDITATION PROGRAM

### Scope of Accreditation

**Legal Name of Accredited Laboratory:** **Public Health Agency of Canada**

Location Name or Operating as (if applicable): National Laboratory for HIV Reference Services

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<b>SCC File Number:</b>	15800
<b>Accreditation Standard(s):</b>	ISO 15189:2012 Medical laboratories – Requirements for quality and competence;
<b>Initial Accreditation:</b>	2008-06-16
<b>Most Recent Accreditation:</b>	2023-08-03
<b>Accreditation Valid to:</b>	2028-06-16
<b>Medical Principal Disciplines:</b>	<b>Microbiology</b> <b>Molecular biology</b>

*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.*

## 1. MICROBIOLOGY

### 1.1 HIV Serology

### 1.2 HTLV Serology

## 2. MOLECULAR BIOLOGY

### 2.1 Molecular Diagnosis – Infectious Diseases

## 3. DETAILS OF SCOPE OF ACCREDITATION

Discipline	Sub-discipline	Analytical principle	Matrix (sample)
1.0 MICROBIOLOGY	1.1 HIV Serology	Qualitative Line Immunoassay	Serum and Plasma
	1.2 HTLV Serology	Qualitative Line Immunoassay	Serum and Plasma
	1.1 HIV Serology	Immunochromatographic Assay	Serum and Plasma
	1.1 HIV Serology	Qualitative Antibody Assay	Serum, Plasma and Whole Blood
	1.1 HIV Serology	Enzyme Immunoassay	Serum and plasma
2.0 MOLECULAR BIOLOGY	2.1 Molecular Diagnosis	Qualitative Nucleic Acid Amplification Test	Plasma and Dried Blood Spots
	2.1 Molecular Diagnosis	Real-Time PCR Assay	Whole Blood
	2.1 Molecular Diagnosis	Quantitative Nucleic Acid Amplification Test	Plasma and Dried Blood Spots
	2.1 Molecular Diagnosis	Quantitative ddPCR	Plasma
	2.1 Molecular Diagnosis	Quantitative Real time PCR	Whole Blood and Cell Pellets

### **Notes:**

This laboratory's scope of accreditation is granted under a flexible scope. The list of methods subject to this type of scope is available upon request from the laboratory.

**HIV:** Human Immunodeficiency Virus

**HTLV:** Human T-Lymphotropic Virus

**PCR:** Polymerase Chain Reaction

**ddPCR:** Droplet Digital Polymerase Chain Reaction



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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Elias Rafoul  
Vice-President, Accreditation Services  
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