

TESTING AND CALIBRATION LABORATORY ACCREDITATION PROGRAM (LAP)

Scope of Accreditation

Legal Name of Accredited Laboratory: Public Health Agency of Canada

Location Name or Operating as (if applicable): National Microbiology Laboratory

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SCC File Number:	15734
Accreditation Standard(s):	ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
Fields of Testing:	Biological
Initial Accreditation:	2005-10-13
Most Recent Accreditation:	2023-11-23
Accreditation Valid to:	2025-10-13

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.

- 15340 - Public Health Agency of Canada, National Microbiology Laboratory, 110 Stone Road West, Guelph, ON, N1G 3W4.
- 151004 - Public Health Agency of Canada, National Microbiology Laboratory, 3400, Boulevard Casavant Ouest, Saint-Hyacinthe, QC, J2S 8E3

Remarque: La présente portée d'accréditation existe également en français, sous la forme d'un document distinct.

Note: This scope of accreditation is also available in French as a document issued separately.

MEDICAL

Medical Testing:

Virology (and Prions)

Program Code	Title	Technique/Equipment	Matrix (sample)	Pathogen/Analyte
BBP-PR-034**	Serological Detection of HEV	Detection of HEV IgM and IgG antibodies using the Wantai HEV-IgM and -IgG ELISA kit	Serum Plasma	Hepatitis E virus
BBP-PR-036**	Serological Detection of HDV	Detection of HDV IgG antibodies using the Wantai HDV -IgG ELISA kit	Serum Plasma	Hepatitis D virus
EV-PR-018	Complete Test Algorithm for Poliovirus Detection and Molecular Characterization	Detection and characterization of poliovirus using isolation, intratypic differentiation and VDPV screening by rRT-PCR and VP1 sequencing	Stool	Poliovirus
IRV-PR-001	Influenza Hemagglutination Inhibition Test	Antigenic strain characterization of influenza viruses using hemagglutination inhibition	Viral culture	Influenza virus
IRV-PR-013	Real-Time RT-PCR Procedures for Genotyping of Influenza Viruses	Genotyping of influenza viruses using real-time RT-PCR	Respiratory specimens Viral culture	Influenza virus
IRV-PR-022	Influenza Antiviral Resistance Testing by Sequence Analysis	Identification of known M gene mutations that confer resistance of influenza isolates to Adamantanes, or NA gene mutations that produce	Viral culture	Influenza virus

		Oseltamivir/Zanamivir resistance in influenza using sequence analysis		
IRV-PR-029	Diagnostic Real-Time RT-PCR Detection of MERS-CoV	Detection of MERS-CoV using real-time RT-PCR	Respiratory specimens	Middle East respiratory syndrome coronavirus (MERS-CoV)
IRV-PR-031	Real-Time RT-PCR Detection of SARS-CoV-2	Detection of SARS-CoV-2 using the E and RdRP targets via real-time PCR	Respiratory specimens	SARS-CoV-2
PDP-RS-037	ELISA of Human Cerebrospinal Fluid (CSF) for Total Microtubule-associated Protein (tau)	Determination of total tau protein concentration in CSF using the Innostest® hTAU Ag kit	CSF	Tau protein
PDP-RS-073	ELISA of Human Cerebrospinal Fluid (CSF) for 14-3-3 Gamma Protein	Determination of 14-3-3 protein concentration in CSF using the Circulex™ 14-3-3 Gamma ELISA kit	CSF	14-3-3 gamma protein
PDP-RS-100	Genomic Sequencing of the PRNP Gene	Genetic sequencing of the human PRNP gene, including identification of codon 129	Whole blood Genomic DNA Brain tissue	Genetic prion diseases
PDP-RS-300	End-Point Quaking-Induced Conversion (EP-QuIC) Assay	Quaking-induced conversion of full-length recombinant hamster prion protein into the disease-associated isoform using human CSF as seed for conversion	CSF	Prion protein
PRVD-PR-004	Smallpox Vaccine Potency Testing	Potency testing of smallpox vaccine by plaque assay	Smallpox vaccine	Smallpox vaccine

RRR-RS-001	Rabies Serum Neutralization Assay	Determination of the levels of rabies neutralizing antibodies using the rabies serum neutralization assay	Serum CSF	Rabies
SP-PR-001	ELISA Protocol for IgM Sin Nombre Serology	Detection of IgM antibodies to Sin Nombre virus using an in-house enzyme-linked immunosorbent assay	Serum Plasma	Sin Nombre virus
SP-PR-002	ELISA Protocol for IgG Sin Nombre Serology	Detection of IgG antibodies to Sin Nombre virus using an in-house enzyme-linked immunosorbent assay	Serum Plasma	Sin Nombre virus
SP-PR-007	PCR Testing in the Special Pathogens Program	Detection of the polymerase (L) and nucleoprotein (NP) genes of ebolavirus species and the glycoprotein (GP) gene of Marburg virus	Whole blood Serum Swab CSF Tissue	Ebola virus Sudan virus Bundibugyo virus Tai Forest virus Marburg virus
VESTD-PR-009**	Human Papillomavirus Genotyping by PCR Amplification and Luminex Detection	Genotyping of a specific L1 region of human papillomavirus using nested PCR and Luminex detection of PCR products	Genital, anal, and oropharyngeal specimens Biopsies	Human papillomavirus
VESTD-PR-011**	Complete Process Method for Varicella Zoster Virus Strain Differentiation	Genotyping of varicella-zoster virus using ORF 38 and 62 to differentiate between wild-type and vaccine strains	Lesion swab Vesicular fluid CSF Whole blood Plasma Viral isolate	Varicella-zoster virus

VESTD-PR-012**	Complete Process Method for Measles Virus Specimens Submitted for RT-PCR	<p>Molecular detection of the measles N and H gene by RT-PCR</p> <p>Detection of measles vaccine virus by RT-PCR</p> <p>Genotyping of measles virus specimens by RT-PCR amplification of a portion of the N gene and sequencing</p>	<p>Urine</p> <p>Nasopharyngeal swab</p> <p>Throat swab</p> <p>Viral isolate</p>	Measles virus
VESTD-PR-013**	Complete Process Method for Mumps Virus Specimens Submitted for RT-PCR	<p>Molecular detection of the mumps fusion gene by real-time RT-PCR</p> <p>Genotyping of mumps virus specimens by RT-PCR amplification of the SH gene and sequencing</p>	<p>Urine</p> <p>Parotid gland/buccal swab</p> <p>Throat swab</p> <p>Saliva</p> <p>Viral isolate</p> <p>Nasopharyngeal swab</p> <p>CSF</p>	Mumps virus
VESTD-PR-014**	Measles / Rubella IgM Serology Testing	<p>Detection of measles IgM antibodies using the Microimmune Measles IgM capture EIA kit</p> <p>Detection of rubella IgM antibodies using the Microimmune Rubella IgM capture EIA kit and/or the Euroimmun Anti-Rubella Glycoprotein IgM ELISA kit</p>	<p>Serum</p> <p>Plasma</p>	<p>Measles virus</p> <p>Rubella virus</p>
VESTD-PR-016**	Rubella IgG Avidity using the Euroimmun Test Kit	Determination of rubella IgG antibody avidity using the Euroimmun Anti-Rubella Virus ELISA IgG kit	<p>Serum</p> <p>Plasma</p>	Rubella virus

VESTD-PR-017**	Determination of Measles IgG antibody production in CSF for SSPE diagnosis	Determination of measles IgG antibodies in CSF using the Euroimmun Measles IgG in CSF kit	Paired CSF and serum	Measles virus
VESTD-PR-018**	Euroimmun IgG ELISA	Determination of rubella IgG antibodies using the Euroimmun Anti-Rubella Virus ELISA IgG kit (Qualitative only)	Serum Plasma	Rubella virus
VESTD-PR-022**	Amplification and quantification of human polyomavirus DNA by quantitative PCR	Quantitative PCR detection of JC virus with primers targeting the viral large T antigen	CSF CNS fresh biopsies Fixed tissue	JC virus
VESTD-PR-030**	<i>Chlamydia trachomatis</i> Detection by qPCR and Genotyping by ompA and pmpH PCR and Direct Sequencing	Differentiation of <i>Chlamydia trachomatis</i> serovars by real-time PCR from confirmed positive specimens and confirmation of LGV strains by direct sequencing of the ompA and pmpH genes.	<i>Chlamydia</i> culture Rectal, endocervical, urethral swabs Urine Biopsies Specimens in Roche Cobas 4800 CTNG buffer Specimens in GEN-PROBE APTIMA buffer	<i>Chlamydia trachomatis</i>
VESTD-PR-036**	Complete Process Method for Rubella Virus Specimens Submitted for RT-PCR	Molecular detection of the rubella E1 and p150 genes by real-time RT-PCR Genotyping of rubella virus specimens by RT-PCR amplification of a portion of the E1 gene and sequencing	Nasopharyngeal swab Throat swab Urine Viral isolate	Rubella virus
VZ-PR-001	West Nile Virus IgM Antibody Capture ELISA (WNV MAC-ELISA)	Detection of West Nile virus IgM antibodies using an in-house enzyme-linked immunosorbent assay	Serum	West Nile Virus

VZ-PR-007	Molecular Detection of Zika Viral RNA in Serum and Urine by Real Time RT-PCR	Molecular detection of the Zika M and E genes by real-time RT-PCR	Serum Urine	Zika virus
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Microbiology (Bacteriology)

Program Code	Title	Technique/Equipment	Matrix (sample)	Pathogen/Analyte
ARNI-PR-001	Antimicrobial Susceptibility Testing of Enteric Pathogens using the Sensititre™ Automated System	Sensititre™ Automated System	Bacterial culture	<i>Salmonella</i> spp. <i>Escherichia coli</i> <i>Campylobacter</i> spp.
BADD-PR-011	Custom Antibiotic Susceptibility Testing	CLSI microbroth dilution susceptibility testing	Bacterial culture	<i>Bacillus anthracis</i> <i>Brucella</i> spp. <i>Burkholderia mallei</i> <i>Burkholderia pseudomallei</i> <i>Francisella tularensis</i> <i>Yersinia pestis</i>
*BADD-PR-018	Real-time PCR Screening Procedure for Security Sensitive Biological Agents	In-house developed real-time multiplex PCR assays	Bacterial culture Whole blood CSF Biopsy tissue Powder Liquid (ricin) Food sample (ricin) Parcels Environmental samples	<i>Bacillus anthracis</i> <i>Brucella</i> spp. <i>Burkholderia mallei</i> <i>Burkholderia pseudomallei</i> <i>Coxiella burnetii</i> <i>Francisella tularensis</i> <i>Ricinus communis</i> Toxigenic <i>Clostridium</i> strains <i>Yersinia pestis</i>

*BADD-PR-019	Real-time PCR Confirmatory Procedure for Security Sensitive Biological Agents	Real-time PCR using in-house differentiating molecular assays	Bacterial culture Whole blood CSF Biopsy tissue Powder Liquid (ricin) Food sample (ricin) Parcels Environmental samples	<i>Bacillus anthracis</i> <i>Brucella</i> spp. <i>Burkholderia mallei</i> <i>Burkholderia pseudomallei</i> <i>Coxiella burnetii</i> <i>Francisella tularensis</i> <i>Ricinus communis</i> <i>Yersinia pestis</i>
*BADD-PR-020	Canonical/Melt-Mama Single Nucleotide Polymorphism Genotyping for <i>B. anthracis</i> , <i>F. tularensis</i> , and <i>Y. pestis</i>	Molecular typing to determine genetic variations between members of a species using canonical single nucleotide polymorphisms.	Bacterial culture	<i>Bacillus anthracis</i> <i>Francisella tularensis</i> <i>Yersinia pestis</i>
*BADD-PR-022	<i>Brucella</i> spp. Canonical Single-Nucleotide Polymorphism Genotyping	Differentiation of <i>Brucella</i> strains via real-time PCR using seven species-specific single-nucleotide polymorphisms	Bacterial culture	<i>Brucella</i> spp.
*BADD-PR-023	Ricin Antigen Capture ELISA	Detection of ricin toxin in biological samples by an in-house enzyme-linked immunosorbent assay	Whole blood Powder Liquid Beans Plant material Food samples Environmental samples	<i>Ricinus communis</i>
BADD-PR-026	MALDI-TOF MS Bacterial Identification	Rapid identification of bacterial colonies by MALDI-TOF mass spectrometry using Biotyper software	Bacterial culture	<i>Bacillus anthracis</i> <i>Brucella</i> spp. <i>Burkholderia mallei</i> <i>Burkholderia pseudomallei</i>

				<i>Francisella tularensis</i> <i>Yersinia pestis</i>
BADD-PR-027/-028/-029	Whole Genome Sequencing for Security Sensitive Biological Agents	Molecular typing using whole genome sequence data based on single base pair variants (SNVs) at specific genomic locations	Bacterial culture	<i>Bacillus anthracis</i> <i>Brucella</i> spp. <i>Burkholderia mallei</i> <i>Burkholderia pseudomallei</i> <i>Francisella tularensis</i> <i>Yersinia pestis</i>
*BADD-PR-030	Multiple SSBA Toxin Detection Assay on the Luminex MAGPIX® Instrument	In-house developed screening assay for Botulinum neurotoxins type \A, \B, \E, and \F, ricin abrin and Staphylococcal enterotoxin type B on the Luminex MAGPIX® instrument	Serum Urine Food Soil Powder Environmental samples	SSBA toxins
DED-PR-050	Identification of Enteric Pathogens	Identification of <i>Aeromonas</i> species using biotyping	Bacterial culture	<i>Aeromonas</i> spp.
		Identification of <i>Arcobacter</i> species using biotyping, 16S rRNA sequencing and MALDI-TOF mass spectrometry		<i>Arcobacter</i> spp.
		Identification of <i>Campylobacter</i> species using biotyping, 16S rRNA sequencing and MALDI-TOF mass spectrometry		<i>Campylobacter</i> spp.
		Identification of <i>E. coli</i> using biotyping, serotyping via agglutination assay, and PCR amplification of the <i>neuC</i> gene for K1 antigen detection		<i>E. coli</i>
		Identification of <i>Helicobacter</i> species using biotyping, 16S rRNA sequencing and MALDI-TOF mass spectrometry		<i>Helicobacter</i> spp.
		Identification of <i>Salmonella</i> species using biotyping and		<i>Salmonella</i> spp.

		serotyping via agglutination assay		
		Identification of <i>Shigella</i> species using biotyping and serotyping via agglutination assay		<i>Shigella</i> spp.
		Identification of <i>Enterobacteriaceae</i> using biotyping		<i>Enterobacteriaceae</i>
		Identification of <i>Vibrio</i> species using biotyping and serotyping via agglutination assay for O1, O139, O75 and O141		<i>Vibrio</i> spp.
DED-PR-350	Genomics-Based Identification and Characterization of Enteric Bacterial Pathogens	Whole genome MLST analysis in Bionumerics	Bacterial culture	<i>E. coli</i> <i>Campylobacter</i> spp. <i>Listeria</i> spp. <i>Salmonella</i> spp. <i>Shigella</i> spp. <i>Vibrio cholerae</i>
		<i>E. coli</i> serotype prediction using whole genome sequencing and ECTyper		<i>E. coli</i>
		<i>Salmonella</i> serotype prediction using whole genome sequencing and SISTR		<i>Salmonella</i> spp.
DED-PR-650	General PCR for Toxin Detection	Toxin typing via PCR amplification of the <i>stx1</i> , <i>stx 2</i> , <i>eaeA</i> and <i>hlyA</i> genes Subtyping of <i>stx2</i> via PCR	Bacterial culture	<i>E. coli</i>
		Toxin typing via PCR amplification of the <i>stx1</i> gene		<i>Shigella</i> spp.
FS-PR-008	The Serological Diagnosis of Lyme Disease	Detection of <i>Borrelia burgdorferi</i> IgM and IgG antibodies using the Zeus Borrelia VlsE1/pepC10 IgG/IgM Test System, Euroimmun EUROLINE <i>Borrelia</i> US (IgM), Euroimmun Anti- <i>Borrelia burgdorferi</i> US EUROLINE-WB (IgG), and Euroimmun anti- <i>Borrelia</i> EUROLINE-RN-AT IgG kits on	Serum	<i>Borrelia burgdorferi sensu stricto</i> <i>Borrelia burgdorferi sensu lato</i>

		the EUROBlotOne Immunoblot Processor		
FS-PR-010	Detection of IgG Antibodies to <i>Anaplasma phagocytophilum</i> in Human Serum by Indirect Immunofluorescent Assay	Detection of <i>Anaplasma phagocytophilum</i> IgG antibodies using the Focus Diagnostics <i>Anaplasma phagocytophilum</i> IFA IgG kit	Serum	<i>Anaplasma phagocytophilum</i>
FS-PR-014	Detection of IgG Antibodies to <i>Bartonella</i> in Human Serum by Indirect Immunofluorescent Assay	Detection of <i>Bartonella henselae</i> and <i>Bartonella quintana</i> IgG antibodies using the Focus Diagnostics <i>Bartonella</i> IFA IgG kit	Serum	<i>Bartonella henselae</i> <i>Bartonella quintana</i>
FS-PR-015	Screening Assay for the Detection of <i>Leptospira</i> IgM Antibodies in Human Serum	Detection of <i>Leptospira</i> spp. IgM antibodies using the Panbio <i>Leptospira</i> IgM ELSIA kit	Serum	<i>Leptospira</i> spp.
NSB-PR-001	SERODIA® TP·PA test for the detection of antibodies to <i>Treponema pallidum</i>	Detection of antibodies to <i>Treponema pallidum</i> using the Fujirebio SERODIA® TP·PA test	Serum	<i>Treponema pallidum</i>
NSB-PR-002	PULSE Scientific Rapid Plasma Reagin (RPR) Screening Test for Syphilis	Determination of lipoidal antibody titres using the PULSE Scientific Rapid Plasma Reagin kit	Serum	<i>Treponema pallidum</i>
NSB-PR-004	BD Difco Venereal Disease Research Laboratory (VDRL) Screening Test for Syphilis	Determination of lipoidal antibody titres using the BD BBL™VDRL Antigen and Control System sets	Serum CSF	<i>Treponema pallidum</i>
NSB-PR-005	ZEUS Scientific FTA-ABS IFA Test System for Syphilis	Detection of antibodies to <i>Treponema pallidum</i> using the Zeus Scientific FTA-ABS IFA Test System kit	Serum	<i>Treponema pallidum</i>

SB-PR-074	PCR and Sequencing of the 16S rRNA gene for Bacterial Identification	Bacterial identification using PCR and 16S rRNA sequencing	Bacterial culture	Bacterial pathogens
SB-PR-075	Antimicrobial Susceptibility Testing on <i>Corynebacterium</i> species and other Coryneforms using Sensititre® Plates	CLSI microbroth dilution susceptibility testing using Sensititre™ plates and the Sensititre AIM™ and Sensititre VIZION™ system	Bacterial culture	<i>Corynebacterium</i> spp. and other Coryneforms
SC-PR-002	Agar Dilution (MIC) Method for Susceptibility Testing of <i>Neisseria gonorrhoeae</i>	Determination of MIC using the agar dilution method	Bacterial culture	<i>Neisseria gonorrhoeae</i>
SC-PR-101	<i>Streptococcus pneumoniae</i> serotyping	Serotyping of <i>Streptococcus pneumoniae</i> using the Quellung reaction	Bacterial culture	<i>Streptococcus pneumoniae</i>
SC-PR-104	Antimicrobial Susceptibility Testing on <i>Streptococcus</i> species using Sensititre® Plates	Susceptibility Testing of <i>Streptococcus</i> species using Sensititre™ plates and the Sensititre AIM™ and Sensititre VIZION™ system	Bacterial culture	<i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i>
SC-PR-200	Genomics-Based Identification and Characterization of Pathogens from the StrepSTI unit	Antimicrobial susceptibility typing of <i>Neisseria gonorrhoeae</i> , serotyping of <i>Streptococcus agalactiae</i> , <i>emm</i> typing of <i>Streptococcus pyogenes</i> , and serotyping and antimicrobial susceptibility typing of <i>Streptococcus pneumoniae</i> using whole genome sequencing	Bacterial culture	<i>Neisseria gonorrhoeae</i> <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i>
TB-PR-007	Microbroth Dilution (MIC) Method for Susceptibility Testing of Rapidly Growing Mycobacteria	CLSI microbroth dilution susceptibility testing using Sensititre™ plates	Bacterial culture	Non-tuberculous <i>Mycobacterium</i> species (NTM)

TB-PR-008	Microbroth Dilution (MIC) Method for Susceptibility Testing of MAI and Slowly Growing Mycobacteria	CLSI microbroth dilution susceptibility testing using Sensititre™ plates	Bacterial culture	Non-tuberculous <i>Mycobacterium</i> species (NTM)
TB-PR-028	MIRU-VNTR, Automated Method	Genotyping of <i>Mycobacterium tuberculosis</i> using Mycobacterial Interspersed Repetitive-Unit Variable Number of Tandem Repeats via capillary electrophoresis	Bacterial culture Genomic extract	<i>Mycobacterium tuberculosis</i>
TB-PR-035	BACTEC MGIT 960 Procedure for Primary Antimicrobials	Susceptibility of <i>Mycobacterium tuberculosis</i> isolates to first line anti- tuberculosis antimicrobials (isoniazid, rifampin, ethambutol, and pyrazinamide) at critical concentrations using the BACTEC™ MGIT™ 960 detection system	Bacterial culture	<i>Mycobacterium tuberculosis</i>
TB-PR-038	BACTEC MGIT 960 Procedure for Second Line Antimicrobials	Susceptibility of <i>Mycobacterium tuberculosis</i> isolates to second line anti- tuberculosis antimicrobials (capreomycin, ethionamide, kanamycin, ofloxacin, PAS, rifabutin, amikacin, moxifloxacin, linezolid, and streptomycin) at critical concentrations using the BACTEC™ MGIT™ 960 detection system.	Bacterial culture	<i>Mycobacterium tuberculosis</i>
TB-PR-040	Real-time PCR Detection of Mycobacterium Species in Clinical Samples	Detection of mycobacterial species using real-time PCR on the QuantStudio	CSF Tissue Sediment from decontaminated samples Culture	<i>Mycobacterium tuberculosis</i>
*TB-PR-045	Cepheid GeneXpert MTB/TB RIF Protocol	Detection of <i>Mycobacterium tuberculosis</i> using the Cepheid GeneXpert MTB/RIF test	Sputum	<i>Mycobacterium tuberculosis</i>

Number of Scope Listings: 64

Notes:

* These test methods can be performed on-site as per RG-Lab.

** Work associated with these test methods is performed at 745 Logan Ave, Winnipeg, MB, R3E 3L5.

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.

Elias Rafoul
Vice-President, Accreditation Services
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