

TESTING AND CALIBRATION LABORATORY ACCREDITATION PROGRAM (LAP)

Scope of Accreditation

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

Location Name or Operating as (if applicable): Biologic and Radiopharmaceutical Drugs Directorate (BRDD), HPFB

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SCC File Number:	15947
Accreditation Standard(s):	ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
Fields of Testing:	Biological Chemical/Physical
Initial Accreditation:	2013-04-29
Most Recent Accreditation:	2022-04-02
Accreditation Valid to:	2025-04-29

CHEMICALS AND CHEMICAL PRODUCTS

(Parenteral Biologics):

Activities carried out relate to physicochemical and biological tests including assay, identity, and purity tests for biological drugs carried out under the authority of the Food and Drugs Act and Regulations.

(Biological Testing – Blood Products):

BGTD-SOP-3127	Potency Testing for Anti-D Immunoglobulin by Competitive ELISA
BGTD-SOP-3146	Potency Assay for Coagulation Factor IX by One-Stage Clot on the BCS-XP
BGTD-SOP-3150	Direct Hemagglutination Method for Anti-A , Anti-B, and Anti-D Antibodies
BGTD-SOP-3180	C1 Esterase Inhibitor Potency Assay on BCS
BGTD-SOP-3191	Potency Assay for Coagulation Factor VIII by One-Stage Clot on BCS-XP
BGTD-SOP-3200	Potency Assay for Coagulation FVIII by Chromogenic Method on BCS-XP
BGTD-SOP-3202	Antithrombin III Potency Determination Assay on the BCS-XP
BGTD-SOP-3203	Potency Assay for von Willebrand Factor-Ristocetin Cofactor (vWF:RCo) on BCS-XP
BGTD-SOP-3219	Alpha-1 Proteinase Inhibitor Potency Assay on the BCS-XP
BGTD-SOP-3221	Potency Assay for Coagulation Factor VIII by One-Stage Clot on ACL TOP 300
BGTD-SOP-3226	Potency Assay for Coagulation Factor IX by One-Stage Clot on ACL TOP 300

(Biological Testing – Vaccines):

BGTD-SOP-3012	BCG Potency Assay
BGTD-SOP-3031	Tissue Culture Potency Test for Yellow Fever Vaccine
BGTD-SOP-3034	Inactivated Polio Vaccine D Antigen ELISA
BGTD-SOP-3070	Potency Testing for Influenza Vaccines by the Single Radial Immunodiffusion (SRID) Method
BGTD-SOP-3104	Tissue Culture Potency Test for Rotavirus Vaccine Using Immunofluorescence
BGTD-SOP-3187	Potency Assay for the Measles, Mumps and Rubella Components of Live Virus Vaccines
BGTD-SOP-3214	In vitro Relative Potency Test for the Recombinant Human Papillomavirus Vaccine (GARDASIL® 9) Using ELISA Assay
BGTD-SOP-3215	Mammalian Cell Line Authentication Using COI-PCR
BGTD-SOP-3225	Inhibition ELISA for the Glycoprotein E Antigen Content of Herpes Zoster Subunit Vaccine

(Physicochemical Testing – Blood Products):

BGTD-SOP-3130	Product Reconstitution Time
BGTD-SOP-3142	Serum Protein Electrophoresis using Helena SPIFE Touch
BGTD-SOP-3158	Purity Assessment of plasma derived products by Size Exclusion Chromatography HPLC
BGTD-SOP-3159	Evaluation of Appearance

Number of Scope Listings: 24

Notes:

BCG: Bacillus Calmette-Guerin

COI-PCR: Cytochrome C oxidase Subunit 1 – Polymerase Chain Reaction ELISA (Enzyme Linked Immunosorbent Assay)

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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Vice-President, Accreditation Services
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