



SCOPE OF ACCREDITATION

Health Canada, HPFB, BRDD
Biologic and Radiopharmaceutical Drugs Directorate (BRDD)
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Ottawa, ON K1A 0K9

Accredited Laboratory No. 772
(Conforms with requirements of ISO/IEC 17025:2005, RG-LAB)

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FIELDS OF TESTING: Biological, Chemical/Physical

INITIAL ACCREDITATION: 2013-04-29

MOST RECENT ACCREDITATION: 2018-10-29

ACCREDITATION VALID TO: 2021-04-29

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-3114	Factor XIII Bioactivity Assay
BGTD-SOP-3127	Potency Testing for Anti-D Immunoglobulin by Competitive Enzyme- linked Immunosorbent assay (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

(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-3132	Measurement of Polysaccharide Content in the Thirteen Valent Pediatric Streptococcus Pneumoniae Vaccine- Prevnar 13 by Rate Nephelometry
BGTD-SOP-3185	Diphtheria Vaccine Serological Potency Assay
BGTD-SOP-3186	Tetanus Vaccine Serological Potency Assay
BGTD-SOP-3187	Potency Assay for the Measles, Mumps and Rubella Components of Live Virus Vaccines
BGTD-SOP-3192	Nimenrix ELISA
BGTD-SOP-3194	Pertussis Mouse Immunogenicity Assay
BGTD-SOP-3214	In vitro Relative Potency Test for the Recombinant Human Papillomavirus Vaccine (GARDASIL® 9) Using ELISA Assay
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 High Performance Liquid Chromatography (HPLC)
BGTD-SOP-3159	Evaluation of Appearance



Standards Council of Canada
Conseil canadien des normes

BGTD-SOP-3176

Content and Aggregates of Factor XIII by Size-Exclusion
Chromatography using HPLC

Number of Scope Listings: 29
SCC 1003-15/947

Notes:

ISO/IEC 17025:2005: General Requirements for the Competence of Testing and Calibration
Laboratories

RG-LAB: SCC Requirements and Guidance for the Accreditation of Testing Laboratories

Elias Rafoul, Vice President
Accreditation Services

Published on: 2020-02-10