



Public Health Agency of Canada

Pathogen and Toxin Licence

Diteba Laboratories Inc

(Name of Organization)

1680 Tech Avenue, Unit 01, Mississauga, Ontario, L4W 5S9

(Address)

Risk Group 2 Human Pathogen and Toxin Licence under section 18 of the *Human Pathogens and Toxins Act*

AND

Risk Group 2 Terrestrial Animal Pathogen Permit under section 160 of the *Health of Animals Regulations*

(Risk group covered by the Licence)

Subject to the conditions annexed hereto

Validity Period: 2021-12-17 to 2026-12-17, *unless otherwise suspended, varied, or revoked.*
Date Issued: 2021-12-17
Issued to: Stefan Mikaelis Overgaard-Thomsen
Biological Safety Officer: Naresh Balachandran

ACTIVITIES - HUMAN PATHOGENS AND TOXINS LICENCE

Subject to the conditions listed below, this licence authorizes the specified activities:

Activities	Biological Agents	Facility description	Type of Work Areas	Animal Species	Condition Names*
Disposing, Exporting, Handling, Importing, Permitting Access to, Possessing, Producing, Storing, Transferring, Using	Risk group 2 human pathogens and toxins	Diteba Laboratories Inc., 1680 Tech Avenue, Mississauga	Containment Level 2: Administrative/Storage Area, Laboratory Work Area, Support Area		CBS CL2, HPTR records and documentation, In vitro, Incident record, Influenza virus - RG2 licences, Movement under HPTR, Prions not allowed, Provision of Information, RG3 and RG4 not allowed, Schedule 5, Toxins

***See Conditions section at the end for full description details. You must also comply with the conditions stated under section 4 of the *Human Pathogens and Toxins Regulations*.**

ACTIVITIES - TERRESTRIAL ANIMAL PATHOGEN PERMIT

Subject to the conditions listed below, this permit authorizes the specified activities:

Activities	Biological Agents	Facility description	Type of Work Areas	Animal Species	Condition Names*
Import, Move to another place	Risk group 2 terrestrial animal pathogens [Excluding pathogens causing Foreign Animal Diseases, emerging diseases and bee diseases] and toxins produced by an animal pathogens	Diteba Laboratories Inc., 1680 Tech Avenue, Mississauga	Containment Level 2: Administrative/Storage Area, Laboratory Work Area, Support Area		Animal introduction denied, CBS CL2, Contact CFIA, HAR records and documentation, In vitro, Incident record, Influenza virus - RG2 licences, Prions not allowed, RG3 and RG4 not allowed, Transfer under HAR

*See Conditions section at the end for full description details.

CONDITIONS

Condition Name	Description
Animal introduction denied	This permit does not authorize the imported material to be introduced into terrestrial animals (laboratory, domestic, or wild).
CBS CL2	This facility requires ongoing compliance with the applicable containment level 2 requirements under the Canadian Biosafety Standard, as amended from time to time.
Contact CFIA	This document does not allow the importation of pathogens causing foreign or emerging animal diseases, aquatic animal pathogens, bee pathogens, and any live animal, animal product and by-product infected by an animal pathogen - contact the Canadian Food Inspection Agency for import and permit requirements for these.
HAR records and documentation	Records and documentation pertaining to animal pathogen import permit requirements for animal pathogens, toxins, and other Health of Animals Regulations-regulated infectious material to be kept on file for a minimum of 2 years following the date of disposal, complete transfer, or inactivation of the imported material.
HPTR records and documentation	Records and documentation pertaining to licence activities involving human pathogens and toxins to be kept on file for a minimum of 5 years.
In vitro	This document authorizes in vitro activities within the type(s) of work area(s) and facility specified above.
Incident record	Records of incidents involving pathogens, toxins, other regulated infectious material, infected animals, or losses of containment to be kept on file for a minimum of 10 years.
Influenza virus - RG2 licences	This document authorizes controlled activities only with Risk Group 2 Influenza A strains, and requires ongoing compliance with the Biosafety Directive for New and Emerging Influenza A Viruses, as amended from time to time.
Movement under HPTR	A person who intends to import, export, transfer, or receive a human pathogen or toxin must communicate that intention to the designated biological safety officer before they make any arrangements for the transaction.
Prions not allowed	This document does not authorize controlled activities with prions.
Provision of Information	The licence holder or biological safety officer must provide the Public Health Agency of Canada requested information relevant to the administration of the Human Pathogens and Toxins Act or the Human Pathogens and Toxins Regulations, in accordance with any conditions specified.
RG3 and RG4 not allowed	This document does not authorize controlled activities with Risk Group 3 and Risk Group 4 pathogens.
Schedule 5	This licence does not authorize controlled activity with any human pathogen or toxin listed in Schedule 5 of the Human Pathogens and Toxins Act.
Toxins	This licence authorizes controlled activities with toxins, including Security Sensitive Biological Agents in amounts equal or below the trigger quantity, within the type(s) of work area(s) and facility specified above.

Condition Name	Description
Transfer under HAR	This document authorizes the imported material to be transferred or moved to another facility which meets the ongoing appropriate containment level requirements under the Canadian Biosafety Standard, as amended from time to time.