Health Canada Santé Canada

Protected B (when completed)
Office of Controlled Substances
July 2018

Test Kit Application Form

(disponible en français)

Privacy Notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. The collection of your personal information is authorized under the Controlled Drugs and Substances Act. This information will be used to process your application for an exemption to use a controlled substance for scientific purposes. Information may be used to provide reports to management. The information may also be used for research, planning, audit and evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the Privacy Act. Failure to provide the requested information may result in a refusal to process the application. This personal information collection is described online at Info Source: Sources of Federal Government and Employee Information Health Canada. In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at privacy-vie.privee@hc-sc.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Canada

1. Application Type

Check the application type below.

New Test Kit Registration	☐	Cancellation of a Test Kit	☐

Note: Only the manufacturer of the test kit can apply for a new test kit registration or the cancellation of an active test kit registration.

When applying for multiple new test kit registrations, sections 1, 3, 4 and 9 need to be completed once only. Sections 5-8 need to be completed for each new test kit registration. When cancelling active test kit registrations, only complete sections 1, 2, 3, 4 and 9.

2. Cancellation(s)

Please complete the following table for any test kit registration numbers that are to be cancelled.

Catalogue Number	Test Kit Number	Brand Name

Additional pages can be attached, if necessary. Check here if additional pages are included**:** ☐

3. Manufacturer's Information

Manufacturer's Name			
Street Address			
City		Province / State	
Postal Code / Zip Code		Country	
Contact Person		Title	
Telephone Number		Email Address	

4. Manufacturer's Mailing Address (if different from section 3)

Street Address			
City		Province / State	
Postal Code / Zip Code		Country	

5. Test Kit Composition

Applicants must verify that proposed substances appear in the schedules of the Controlled Drugs and Substances Act (CDSA) or its regulations. For substances that are not listed, applicants must provide confirmation from the Status Confirmation of Substances Section of Health Canada (hc.status-demandedestatut.sc@canada.ca) indicating that the substance is controlled under the CDSA. Failure to include this confirmation with your application may result in it being returned to you as incomplete.

Brand Name of Test Kit					
Catalogue Number					
Controlled Substance(s)				**Other Substance(s)**	
Substance	**CDSA Regulation**	**Form**	**Quantity or Concentration**	**Substance**	**Quantity or Concentration**
e.g. D, L-amphetamine	e.g. Narcotic Control Regulations	e.g. Methanol solution	e.g. 1 mg/ml	e.g. BSA	e.g. 1 mg/ml

Check here if additional information regarding contents of Test Kit is included: ☐

6. Test Kit Use (select all that apply)

Medical ☐
Laboratory ☐
Industrial ☐
Educational ☐
Research ☐
Law Administration/Enforcement ☐

7. Sample of the Test Kit Label

The manufacturer's name, brand name of the test kit, and location where the test kit number will appear must be clearly indicated on the label.

All information on the label must be an exact match of the information provided in this application.

Check here if a copy of the label is attached: ☐

8. Test Kit Design and Construction

Provide a description of the design and construction of the proposed test kit (i.e., contents of the kit). A copy of the package insert or instructions for use should be attached if available.

Check here if a copy of the package insert or instructions are included: ☐

9. Declaration

I hereby declare that the information provided in this application and in any attached documentation is correct and complete.

I hereby declare that the contents of the test kit(s) above are not intended, or likely to be consumed by, or administered to, a human or an animal.

Surname (last name)		**Given Name(s)**	
Title			
Signature		Date	(YYYY/MM/DD)

10. Submission

Submit this completed form and any supporting documentation to the Office of Controlled Substances (OCS) at the address below. Should you wish to have your authorization(s) sent by courier, you must provide the waybill(s) with your application.

Controlled Drugs Section
Authorizations Division
Office of Controlled Substances
Health Canada
AL 0300B
161 Goldenrod Drwy
Ottawa ON K1A 0K9