Health Canada Santé Canada

Guidance Document

Interim Compliance Approach Regarding the Testing of Semen Donors for *Treponema pallidum* (Syphilis)

Published by authority of the
Minister of Health

Date adopted	2016-11-01
Effective date	2016-11-01

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	Our mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

© Minister of Public Works and Government Services Canada 2016

Available in Canada through

Health Canada – Publications
Address Locator 0900C2
Ottawa, Ontario
K1A 0K9

E-mail: publications@hc-sc.gc.ca
Telephone: 613-957-2991, 1-866-225-0709
Fax: 613-941-5366
Teletypewriter: 1-800-465-7735 (Service Canada)

Également disponible en français sous le titre :

Catalogue No.

ISBN

Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

Table of Contents

1. Introduction

Health Canada is notifying establishments who process and/or import donor semen for distribution of its interim compliance approach with respect to the requirements for testing donors for *Treponema pallidum* (syphilis) as established by the *Processing and Distribution of Semen for Assisted Conception Regulations* ("Semen Regulations").

As required by subparagraph 9(1)(a)(ii) of the Semen Regulations, every person who processes semen for distribution must perform, among other tests, the minimum serological testing on semen donors as part of the donor screening process. Further, paragraph 5(a) of the Semen Regulations requires every person who imports semen for distribution to ensure that, among other things, the semen meets the processing requirements which include the minimum serological testing on semen donors. The details of the testing requirements are set out in the *Health Canada Directive: Technical Requirements for Therapeutic Donor Insemination* ("Directive"), which is incorporated by reference in the Semen Regulations.

Clause 3.5.2(f) of the Directive states that donors must be tested for syphilis using both a non-treponemal test and a treponemal-specific test. Furthermore, clause 3.5.1.1(c) requires that the serological tests specified in clause 3.5.2, which includes testing for syphilis, must be performed with donor screening test kits approved or licensed under the Canadian Medical Devices Regulations, if such test kits are available through the accredited laboratory, or with diagnostic test kits that have been approved or licensed under the Canadian Medical Devices Regulations, in any other case.

This approach to testing donors for syphilis infection is inconsistent with that employed in Canada for other human cells, tissues and organs, and is inconsistent with international standards, most notably those in the United States, from where the majority of donor semen used in Canada is imported.

Therefore, on an interim basis, until the Semen Regulations are amended to adopt a more modern testing approach, Health Canada's compliance approach with respect to testing donors for syphilis will be to prioritize enforcement activities on a risk-mitigation basis in order to most appropriately apply its departmental resources and capacity.

1.1. Policy Objectives

Health Canada acknowledges the need to update the Semen Regulations and is actively engaged in policy work to do so. The syphilis testing requirements is one aspect of the Semen Regulations which Health Canada intends to review and amend.

The objective of this interim compliance approach is to ensure that semen donors are tested for syphilis in accordance with the latest scientific knowledge, while ensuring that Canadians continue to have access to safe donor semen to help them build their families.

1.2. Scope and Application

This interim compliance approach applies to Canadian establishments who process and/or import for distribution donor semen for use in assisted conception.

2. Guidance for Implementation

With respect to the requirements set out in the Semen Regulations for testing semen donors for syphilis, Health Canada will, effective immediately, prioritize its resources by directing them to situations that represent the higher risk to human health. Although action can be taken by Health Canada at any time in response to non-compliance with the Semen Regulations, under this graduated compliance approach the Department will apply a low enforcement priority to non-compliant donor semen that it considers to be of low risk to human health.

At this time, Health Canada considers donor semen to be of low risk to human health if the following measures are taken for testing donors for syphilis:

1. The use of syphilis tests that are licensed either:
    a. in Canada, if the testing is performed in Canada; or
    b. in Canada or the United States, if the testing is performed outside Canada; and

2. The use of either a treponemal-specific test or a non-treponemal test.

    Note: Donor semen may be released for distribution if: (i) the donor's initial and post-quarantine blood samples are negative using a non-treponemal test; or (ii) if these blood samples are positive using a non-treponemal test, but negative using a treponemal-specific confirmatory assay. It should be noted that if establishments decide to use a treponemal-specific assay for syphilis as the test of record, the semen shall not be released for distribution if the donor's specimen is positive. This is because a positive treponemal-specific test identifies both recent syphilis infections, and remote or treated syphilis infections. While a non-treponemal test can be performed to rule out a recent infection, false negative results cannot be ruled out. Thus, establishments need to develop and employ appropriate testing algorithms to resolve this issue.

This approach to testing donors for syphilis infection is consistent with that employed in Canada for other human cells, tissues and organs.

Any other non-compliance with the Semen Regulations with respect to testing donors for syphilis would be considered to be of high risk to human health.

3. Regulatory Requirements

Canadian establishments that process and/or import donor semen for distribution are responsible for ensuring that donors are screened in accordance with the requirements in

the Semen Regulations and may use Health Canada guidance, including this one, to help interpret those requirements.

Pursuant to the Directive, it is the Medical Director at the relevant establishment, and not Health Canada, who makes the determination that donor semen has been processed in accordance with the regulatory requirements and is suitable for distribution.

4. Compliance and Enforcement

Designated inspectors exercise powers under Section 23 of the *Food and Drugs Act*. Designated inspectors have the authority to carry out inspections in order to assess a site's compliance with legislative requirements. In such circumstances, pursuant to subsection 23(3) of the *Food and Drugs Act*, owners or persons in charge of a place entered by an inspector and every person found therein must give all reasonable assistance and furnish the inspector with any information the inspector may reasonably require.

The Regulatory Operations and Regions Branch (RORB) takes a risk-based approach to compliance and enforcement activities. When non-compliance is identified, the primary objective of the response strategy is to manage the risk to Canadians and use the most appropriate level of intervention to ensure that the responsible regulated party brings the product or activity into compliance. RORB evaluates instances of non-compliance, taking into consideration the level of risk, among other factors, to determine the most appropriate action(s) to be taken.

5. Contact Information

5.1. Clinical Trials and Biological Product Compliance Unit

Inquiries and information requests regarding this interim compliance approach should be submitted directly to the Clinical Trials and Biological Product Compliance Unit, RORB by email: BPCP-PCPB@hc-sc.gc.ca.

5.2. Adverse Reaction Reporting

Pursuant to section 14 of the Semen Regulations, where a physician who performed assisted conception on a woman has reasonable grounds to believe that an infectious agent was transmitted to the woman through semen used in the performance of the assisted conception, the physician among other things must report suspected transmissions of an infectious agent by donor semen to the processor of the semen. The semen processor is then responsible, pursuant to section 15 of the Semen Regulations, for reporting certain information to the Minister of Health by sending a copy of the report to the Minister.

More information about adverse reaction reporting may be found at the following link: http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/reaction-eng.php#Semen