

August 15, 2007

ATTN: Medical Health Officers and Branch Offices

Public Health Nursing Administrators and Assistant Administrators

Holders of Communicable Disease Control Manual

Re: Revisions to Chapter 5 of the CD Manual - Point of Care HIV Test Guidelines

Please note the following revision to the Communicable Disease Manual, Chapter 5 – Sexually Transmitted Infections – Point of Care HIV Test Guidelines

Page 2, Notes Section:

- As of August 2007, external quality control measures are in place for bioLytical Laboratories Inc.
- Statement "Please note that an external quality control process does not eliminate requirements for on-site quality assurance activities to ensure appropriate use and interpretation of POC test kits" (added after recommendation that external quality control measures be in place)

An external quality control process has been established between Providence Health Care and bioLytical Laboratories Inc, for quality control testing of the INSTI HIV-1 Rapid antibody test. Testing will be performed on test kits from each batch manufactured, using known positive and negative sera for HIV. Results of the external quality control process will be reported to the BCCDC and the Provincial Health Officer.

Please note that this process will monitor the performance of the INSTI HIV-1 Rapid antibody test kits to ensure that they continue to perform within licensed test performance characteristics. This external quality control process does not eliminate the need for quality assurance activities at the point-of-care, which will ensure that the test is being used and interpreted correctly. Please refer to section 10 of these guidelines for more information about quality assurance activities.

Administrative Circular #2007: 12

Please remove and destroy the following pages from the Communicable Disease Manual, Chapter 5 – Point of Care HIV Test Guidelines

Page 2 dated April 2007

Insert the following pages in the Communicable Disease Manual, Chapter 5 – Point of Care HIV Test Guidelines

Page 2 dated August 2007

If you have any questions or concerns, please contact Dr. Mark Gilbert, Physician Epidemiologist, at telephone (604) 660-6149, fax (604) 775-0808 or by email at mark.gilbert@bccdc.ca

Sincerely,

Dr. Michael L Rekart, Director

Muhael Z. Rehart

Division of STI/HIV Prevention and Control

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