

CUN-19-007

Customer Update Notice

Date: 19-SEP-2019

Re: Part Number: 90-1008 INSTI HIV-1/HIV-2 Antibody Test, Canada

Please be advised that the Intended Use of INSTI® HIV-1/HIV-2 Antibody Test, part number 90-1008 marketed in Canada is amended to allow for the use of INSTI HIV test kit by any health care professionals at point-of-care (POC) settings including doctors' offices, clinics, care facilities or community outreach programs. Instructions For Use (IFU part number 50-1028) is revised to reflect this amendment

INSTI® HIV-1/HIV-2 Antibody Test was approved by Health Canada in 2005. At the time of its approval, the test was designated for use only in medical settings according to the Intended Use statement. This also meant that only trained healthcare professionals such as doctors, nurses and laboratory technicians were permitted to perform the test.

The INSTI HIV-1/HIV-2 Antibody Test delivers instant, accurate results from a one-minute procedure. The significance of this amendment is that it provides more access to HIV testing through the expansion in the range of healthcare professionals able to perform INSTI, including HIV counselors, and peer testers.

Please note that for a limited period, you may still receive product with an older version of the IFU.

Please contact bioLytical Laboratories Inc. customer support if you have any questions or concerns at +1-866-674-6784, or by email at customercare@biolytical.com.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Larry Murphy', with a stylized flourish at the end.

Mr. Larry Murphy

VP, Quality and Regulatory Affairs