



CUN-19-005 Rev. 1

Customer Update Notice

Date: 26-AUG-2019

Re: INSTI® HIV-1/HIV-2 Antibody Test

Please be advised that a specific lot of INSTI® HIV-1/HIV-2 Antibody Test, Part Number 90-1008 has reported reactive or false positive results at a rate that is above historical trends. The following lot may be impacted:

INSTI Lot Number	Expiration date
1008190059	2020-05-06

This lot meets the performance claims as stated in the Instructions for Use. Customers should continue to test and interpret results based on the information provided in the Instructions for Use.

No actions are required by the customer at this time. bioLytical Laboratories Inc. continues to monitor the product performance.

Please contact bioLytical Laboratories Inc. customer support if you have any questions or concerns at +1-866-674-6784 Ext. 200, or by email at customercare@biolytical.com

Sincerely,

Larry Murphy

Vice President of Quality and Regulatory