

INSTI Test Kit - New Lot Validation Record

INSTI Kit									
Lot Number	Expiry Date	Insert ID	Date Received	Date Tested	Test Results	Control Lot #	Controls Expiry Date	Program Comments at Verification	Site - Reported Problems
1008190314	26-Nov-20	51-1028M 10 Jan 2019 ©2019	20-Sep-19	10	OK	1035190147	7-May-20	IgG controls large, solid blue. Anti-HIV-1 control is double the strength of the anti-HIV-2 control (weak reactive). Patient positive pools are weaker than the anti-HIV-2 control. All nonreactive results were clearly non-reactive.	
1008190389	6-Feb-21	51-1028M 10 Jan 2019 ©2019	26-Nov-19	16	OK	1035190269	9-Aug-20	IgG control is strong, large, solid blue. Nonreactive controls and pools all cleanly nonreactive. Anti_HIV-1 control is slightly stronger than the anti-HIV-2 control. Both are weaker than the verification panel positives. All 3 patient pools (Pos) are weak.	
1008200076	14-May-21	51-1028N 19 Sep 2019 ©2019	2-Mar-20	15	OK	1035190269	9-Aug-20	Change to manufacturer's insert: Slight formatting changes and addition of section at the end related to untrained user. No changes needed for existing documents. Problems? 1 membrane for a weak positive result showed a test spot very close to the edge of the membrane unit. This could make interpretation difficult for some testers. IgG control was large, dark blue, solid. Negative controls and samples were clearly non-reactive. Positive samples and controls showed appropriate variation in strength.	
1008200147	18-Jun-21	51-1028N 19 Sep 2019 ©2019	20-May-20	21-May-20	OK	1035200059	2-Mar-21	IgG control large and blue. Negative samples cleanly negative. Positive reactions of variable, and acceptable, strength.	
1008200211	20-Jul-21	51-1028N 19 Sep 2019 ©2019	24-Sep-20	29-Sep-20	OK	1035200059	2-Mar-21	IgG weaker than usually seen and location shifts a bit at the top of the membrane. Samples tested per expectations. Negative results all cleanly negative	