

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 |
| 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 | |
| 1008200288 | 3-Feb-22 | 51-1028N 19 Sep 2019 ©2019 | 7-Dec-20 | 9-Dec-20 | OK | 1035200059 | 2-Mar-21 | IgG spots are medium in colour and size, but are solid spots. HIV negative controls and samples are cleanly non-reactive. Patient positive pools are all weak and weaker than the manufacturer's controls. Anti-HIV-1 pos control is stronger than the Anti-HIV-2 pos control. | |
| 1008210051 | 9-May-22 | 51-1028N 19 Sep 2019 ©2019 | 22-Mar-21 | 23-Mar-21 | OK | 1035200285 | 27-Nov-21 | Some variability in the size of the IgG control spots. Reactives are weaker than usual, but still clearly visible. Positive controls and samples show appropriate variability. Negative samples cleanly negative. | |