# **Appendix A – Inclusion and Exclusion Criteria**

Inclusion criteria:

* Participants presenting for voluntary testing for HIV infection in the clinic or community-based setting
* Able to understand and complete study informed consent; able to sign or instruct the study research coordinator to sign the informed Consent form
* Able to complete required testing procedures in one session on the allocated testing day;
* Able to speak, read, and write in English or French
* Person is ≥18 years of age
* Willingness to participate in the study site’s standard of care HIV counselling and testing program and receive the study site’s standard of care test results
* Willingness to participate in providing the necessary volume of whole blood collected through venous blood draw (approximately 7 ml) and finger stick for use in the study protocol testing methods

Exclusion criteria:

* Are known HIV positive
* Do not meet the inclusion criteria
* Have received any experimental HIV vaccine
* Are currently on a PrEP regimen
* Have participated in any prior, or concurrent trial of HIV self-tests
* A practicing medical healthcare professional (doctor, nurse or HIV Counsellor that performs HIV testing with Rapid Tests)
* Has used an RDT for self-testing previously

# **Appendix B – Exclusion List**

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| **Study Exclusion List (n=89)** |
| **EXCLUSIONS FROM ALL ANALYSES (n=47)** |
| **1. Missing PID in Qualtrics (n=22)** |
| ON01-007, 052, 190, 259, 272, 289, 303, 304, 316, 317, 318, 331, 343, 350, 358, 380 |
| ON02-061, 064, 070, 071, 084 |
| QC01-046 |
|  |
| **2. Result of enrollment: withdrawn (n=2)** |
| ON01-026, 027 |
|  |
| **3. No self-test/mock test (n=23)** |
| ON01-019, 150, 274, 287, 308, 334 |
| ON02-003, 004, 013, 031, 032, 038, 044, 046, 050, 054, 068, 075, 088, 090, 094 |
| MB01-113 |
| QC01-007 |
|  |
| **EXCLUSIONS FROM PRIMARY EFFICACY AND USABILITY ANALYSES (n=12)** |
| **4. No self-test result (n=12)** |
| ON01-051, 054, 055, 056, 116, 157, 197 |
| ON02-052 |
| MB01-137 |
| QC01-011, 064, 109 |
|  |
| **FURTHER EXCLUSIONS FROM PRIMARY EFFICACY ANALYSES (n=30)** |
| **5. No self-test result (complete self-test data but no participant interpretation) (n=9)** |
| ON01-001, 002, 004, 013, 016, 025, 028, 037, 046 |
|  |
| **6. No lab result (n=9)** |
| ON01-011, 320, 336, 341, 362, 395, 397 |
| ON02-009, 012 |
|  |
| **7. Poured bottle 1 into bottle 2 before adding to test device (n=12)** |
| ON01-336, 355, 368, 369, 377, 370, 371, 372, 390, 398 |
| ON02-081, 086 |
| Note: Coding for Sites |
| ON01: Hassle Free Clinic |
| ON02: Women's Health in Women's Hands |
| MB01: Nine Circles Community Health Centre |
| QC01: Clinique Médicale l'Actuel |