

Comparison of Rapid Testing Technology Offered by N.C. Rapid Testing Program

|   |                                    | OraSure Technologies<br>OraQuick <i>ADVANCE</i> ®<br>Rapid HIV-1/2<br>Antibody Test | Diagnostics Direct<br>Syphilis Health<br>Check™ | OraSure<br>Technologies<br>OraQuick® HCV<br>Rapid Antibody Test | INSTI HIV-1/HIV-2<br>Antibody Test  | Chembio DPP<br>HIV-Syphilis         |
|---|------------------------------------|---|---|---|-------------------------------------|-------------------------------------|
| Specimen<br>Collection  | Venipuncture<br>Whole Blood        | Yes   | No  | No  | Yes                                 | Yes                                 |
|   | Fingerstick<br>Whole Blood         | Yes   | Yes   | Yes   | Yes                                 | Yes                                 |
|   | Plasma                             | Yes   | Yes   | Yes   | Yes                                 | Yes                                 |
|   | Serum                              | No  | Yes   | Yes   | No                                  | No                                  |
|   | Oral Fluid                         | Yes   | No  | No  | No                                  | No                                  |
| Complexity  | Waived                             | Oral fluid, Fingerstick<br>whole blood,<br>Venipuncture Whole<br>Blood              | Fingerstick whole<br>blood                      | Fingerstick whole<br>blood, Venipuncture<br>whole blood         | Fingerstick whole<br>blood          | Fingerstick whole<br>blood          |
|   | Moderate                           | Plasma  | Venipuncture whole<br>blood, Plasma,<br>Serum   | N/A   | Venipuncture whole<br>blood, Plasma | Venipuncture whole<br>blood, Plasma |
| Shelf Life  | Control Kits                       | 12 months unopened<br>8 weeks opened  | 24 months                                       | 12 months unopened<br>8 weeks opened                            | 12 months                           | 24 months                           |
|   | Test Kits                          | 24 months   | 24 Months                                       | 18 months   | 15 months                           | 24 months                           |
| Temperature<br>Requirements   | Control<br>Storage                 | 2° to 8°C<br>(35° to 46°F)  | 2° to 8°C<br>(35° to 46°F)                      | 2° to 8°C<br>(35° to 46°F)                                      | 2° to 30°C<br>(35.6°-86°F)          | 2° to 8°C<br>(36° to 46°F)          |
|   | Test Kit<br>Storage                | 2 to 27°C<br>(35° to 80°F)  | 4° to 30°C<br>(39.2°-86°F)                      | 2° to 30°C<br>(35.6°-86°F)                                      | 2 to 30°C<br>(35° to 86°F)          | 2° to 25°C<br>(36° to 77°F)         |
|   | Testing<br>Environment             | 15° to 37°C<br>(59° to 99°F)  | 20° to 26°C<br>(68° to 78.8°F)                  | 15° to 37°C<br>(59° to 99°F)                                    | 15° to 30°C<br>(59°-86°F)           | 18° to 25°C<br>(64° to 77°F)        |
| Time  | Minimum Time<br>for<br>Development | 20 minutes  | 10 minutes                                      | 20 minutes  | 1 minute                            | 15 minutes                          |
|   | Read Window                        | 20 to 40 minutes  | 10 to 20 minutes                                | 20 to 40 minutes  | 1 to 5 minutes                      | 15 to 25 minutes                    |
| Sensitivity<br><small>(95% confidence limits for<br/>HIV 1)</small> | Venipuncture<br>Whole Blood        | 99.6%   |   |   | 99.9%                               | 99.5% (HIV)<br>96.5% (Syphilis)     |
|   | Fingerstick<br>Whole Blood         | 99.6%   | 98%   | 98%   | 99.8%                               | 99.4% (HIV)<br>94.7% (Syphilis)     |
|   | Plasma                             | 99.6%   | 99.9%   | N/A   | 99.9%                               | 99.3% (HIV)<br>96.8% (Syphilis)     |
|   | Serum                              | N/A   |   | N/A   | N/A                                 | N/A                                 |
|   | Oral Fluid                         | 99.3%   | N/A   | N/A   | N/A                                 | N/A                                 |

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|  |                          | <b>OraSure Technologies OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test</b>        | <b>Diagnostics Direct Syphilis Health Check™</b>                                     | <b>OraSure Technologies OraQuick® HCV Rapid Antibody Test</b> | <b>INSTI® HIV-1/HIV-2 Antibody Test</b>  | <b>ChemBio DPP HIV-Syphilis</b>  |
|--|--------------------------|--|--|---|--|--|
| Specificity<br>(95% confidence limits)   | Venipuncture Whole Blood | 100%   | 100%   | 98%   | 100%   | 99.5% (HIV)<br>94.3% (Syphilis)  |
|  | Fingerstick Whole Blood  | 100%   | 99.5%  | 98%   | 99.5%  | 99.6% (HIV)<br>95.5% (Syphilis)  |
|  | Plasma                   | 99.9%  | 100%   | 98%   | 100%   | 99.6% (HIV)<br>93.9% (Syphilis)  |
|  | Serum                    | N/A  | N/A  | 98%   | N/A  | N/A  |
|  | Oral Fluid               | 99.8%  | N/A  | N/A   | N/A  | N/A  |
| Detection Time Frame*<br>Days <b>after</b> HIV-1 RNA is detectable (~10 days)  |                          | 23.7 days  | N/A  | N/A   | 21 days  | 14-28 days   |
| HIV-2 Detection  |                          | Yes  | N/A  | N/A   | Yes  | Yes  |
| Materials Provided in Test Kit (not including manufacturer supplied paperwork) |                          | Test device, developer solution, reusable test stands, specimen collection loops | Test device, disposable pipettes, diluent in dropper bottle containing saline buffer | Test device, buffer, pipette, moisture pad                    | Test device, membrane Unit, bottle 1, sample diluent (1.5ml), Bottle 2, color developer (1.5ml), bottle 3, clarifying solution (1.5ml), lancet, capillary test pipette, alcohol swab | Test device, desiccant pouch, disposable 10 uL Sample loop, 1mL phosphate buffer (Black cap), 6mL phosphate buffer (Green cap) |
| Available Kit Sizes  |                          | 100 test kits<br>25 test kits  | 20 test kits   | 25 test kits  | 50 test kits   | 20 test kits   |
| Generation of detection  |                          | 3rd generation lateral flow  | N/A  | N/A   | 3rd generation immunofiltration "flowthrough"  | 3rd generation   |

\*Median of 95% confidence intervals representing the estimated ranges of days that HIV-1 tests begin to detect HIV-1 infection AFTER HIV-1 RNA is detectable. The interval between HIV infection and the appearance of HIV-1 RNA is estimates to be around 10 days, but the absolute range is not yet known. See [https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages\\_1.pdf](https://www.cdc.gov/hiv/pdf/testing/hiv-tests-advantages-disadvantages_1.pdf) for further details.

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