



Mission Critical HIV Screening Solution.



FDA Approved, CLIA Waived!

OraQuick[®] Rapid HIV-1 Antibody Test



The first truly rapid point-of-care test that is FDA approved and CLIA waived.

It's quick.

- Lab quality results after 20 minutes.

It's simple to use.

- Just three steps yield an easy to read result.

It's changing the future of HIV testing.

- Testing and counseling in one visit.

A major breakthrough for HIV-1 testing:

- FDA Approved.
- CLIA waived
- Accurate Test Results After Just 20 Minutes.
- Greater than 99% Accurate.
- Portable.
- Fingertick Blood Sample Collection.

Performing the OraQuick[®] Rapid HIV-1 Antibody Test



- 1. Collect**
Touch the specimen collection loop to the fingerstick blood droplet.



- 2. Mix**
Use the loop to stir the specimen in the vial of developer solution.



- 3. Read**
Insert the device into the vial and read the results after 20 minutes.

Reading an OraQuick[®] Rapid HIV-1 Antibody Test Result



■ Example of a Non-Reactive test result:

- Only the control (C) area shows a line.
- No line is present in the test (T) area. Test result is interpreted as NEGATIVE FOR HIV-1 Antibodies

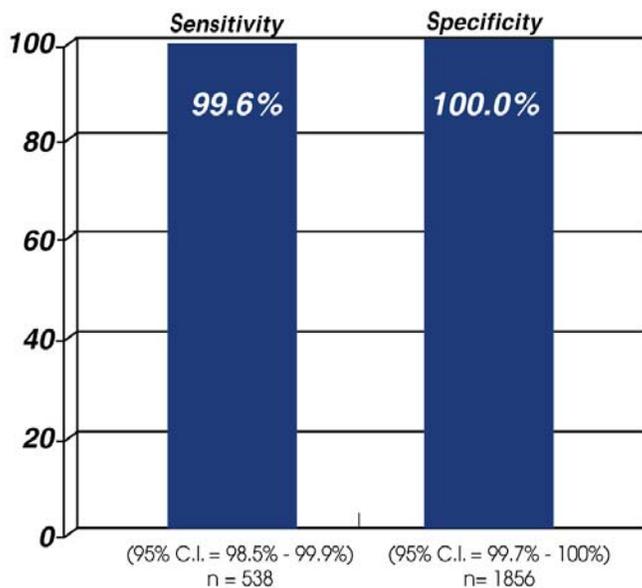


■ Example of a Reactive test result:

- Lines appear in both the control (C) test (T) areas.
- Test result is interpreted as PRELIMINARY POSITIVE FOR HIV-1 Antibodies

Clinically proven quick and easy to use, the OraQuick[®] Rapid HIV-1 Antibody Test is greater than 99% accurate

■ Fingerstick Whole Blood Clinical Trial Results



Accuracy

A double-blind, multi-center, clinical study was conducted at sites of intended use in areas of high and low prevalence, and with subjects reported to be HIV positive, using the OraQuick[®] Rapid HIV-1 Antibody Test. The overall sensitivity and specificity of the assay in this study was 99.6% and 100%, respectively, using whole blood from a fingerstick.

OraQuick® Rapid HIV-1 Antibody Test Kits

OraQuick® Rapid HIV-1 Antibody Test Kits are available in the following packaging configurations:

| Kit Size | 100 count | 25 count |
|---|-----------|-----------|
| Item No. | 1001-0051 | 1001-0052 |
| Divided pouches, each containing: Test Device (1) Absorbent Packet (1) Developer Solution Vial (1) (each vial contains 1 mL of a phosphate buffered saline solution containing polymers and an antimicrobial agent) | 100 | 25 |
| Reusable Test Stands | 10 | 5 |
| Specimen Collection Loops | 100 | 25 |
| Subject Information Pamphlets | 100 | 25 |
| Package Insert | 1 | 1 |
| Customer Letter | 1 | 1 |

| | |
|---|---|
| Device Test Storage Requirements | 2—27°C |
| Test Sample Type (Size) | Fingerstick Whole blood (5 micro liters) |
| National Stock # | 100 test kit: 6550-01-502-6235 25 test kit: 6550-01-502-6241 |
| CLIA Complexity | Waived |
| Test Type | Qualitative Immunoassay |
| CPT Code | 86701 HIV-1 |



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