Food and Drug Administration (FDA) Sales Restrictions

To help ensure the quality of testing with the OraQuick test, the FDA approved the test kit with specific restrictions for its sale. These restrictions apply to the sales of waived test kits. By purchasing the test, the customer agrees to follow these restrictions, outlined below. For the specific FDA language, refer to the OraQuick package insert.

The kit purchaser must:

1. Be a clinical laboratory, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate and NYS DOH certification that is required by the Clinical Lab Evaluation Program (CLEP)
2. Have an established quality assurance program.
3. Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
4. Provide information to persons being tested by giving each a copy of the manufacturer's "Subject Information" pamphlet prior to specimen collection and appropriate information when providing the test results.
5. Not use the kit to screen blood or tissue donors.

Each site must:

1. Have a valid CLIA certificate of waiver, certificate of compliance or certificate of accreditation.
2. Follow the manufacturer's instructions for performing the test.
3. Permit announced or unannounced inspections by representatives of the CLEP program under certain circumstances.
4. Perform only waived tests if registered as a Limited Testing Site.