



**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

November 7, 2005

Dear Valued Customer:

Subject: OraSure Technologies, Inc. October Notification

Recently you received a customer letter from OraSure Technologies, Inc. informing you that we were reducing the expiration dating from our OraQuick ADVANCE Rapid HIV-1/2 Antibody Testing and OraQuick rapid HIV-1 Antibody test from eight (8) months to six (6) months. This reduction in expiration dating resulted from a specificity parameter failure in one lot at seven (7) months and a temperature of 30°C (86°F). The stability testing that was conducted included sensitivity testing, which passed for this lot.

The sensitivity of a test is what measures its ability to identify HIV antibodies. Because this lot passed all sensitivity stability specifications we do not feel that HIV infection would have been missed by the assay and we did not recommend retesting of individuals tested utilizing these lots. The specificity of the test is what predicts the number of false positives that *may* occur. Essentially, this is non-specific binding that may be seen in a clinically negative population. This is the specification that did not meet our stability criteria. If there had been an increase in the number of false positives, those individuals would have required a confirmation test and subsequently found to be negative. To date, our data from the field demonstrates that our devices are still performing within the labeling claim for specificity of 99.8% (95% C.I. = 99.6% - 99.9%) for oral fluid, 99.9% (95% C.I. = 99.6% - 99.9%) for plasma and 100% (95% C.I. = 99.7% - 100%) for finger stick whole blood.

OraSure is committed to ensuring that HIV testing conducted in your facility is minimally impacted by this reduction in shelf-life. We will work with you through our customer service department to ensure that your product that has expired or with an immediate expiration date due to the decrease in shelf-life is replaced. You will need to contact our customer service center at 1-800-ORASURE (800-672-7873) and work with one of our customer representatives to initiate this process.

Sincerely,

OraSure Customer Care