Customer Letter

Date:

Customer Name
Company Name
Address
City, State ZIP

Subject: Important Shelf-Life Information Regarding the OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test and OraQuick® Rapid HIV-1 Antibody Test

Dear Customer Name:

In October of 2005, OraSure Technologies, Inc. performed routine annual stability testing on the OraQuick Rapid HIV test. During this on-going stability testing at 7 months, we confirmed that for one lot, our testing at 30°C (86°F) indicated a failure for one parameter related to specificity. Our stability testing for this lot at refrigerated and room temperature passed all specifications. Sensitivity testing at each of the above storage conditions associated with this same lot passed all specifications.

To date, our data from the field demonstrates that our devices are 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.

We are confident that our devices are performing as indicated in our package insert. However, at this time, we have decided that the expiration dating of our devices be reduced from eight (8) months to six (6) months.

According to our records, you received test devices from the following pouched device lots:

[Insert table with lot number, original and revised expiration dating]

We apologize for any inconvenience this may cause you and/or your organization. We at OraSure Technologies, Inc. understand the importance of your efforts and are committed to working with you to minimize the impact in anyway that we can. Please feel free to call us at 1-800-ORASURE directly, should you have any concerns or questions.

Sincerely,

Sue Sutton-Jones
Senior Vice President, RA/QA
OraSure Technologies, Inc.