

**Frequently Asked Questions Re: OraQuick® ADVANCE™ HIV Test
January 10, 2006**

See “Important Information Regarding the Answers to Frequently Asked Questions” Below

- 1. There were a number of stories in the media in December 2005 about clinics that have reported false positive results while using OraQuick® ADVANCE™ with oral fluid. Isn't a certain percentage of false positives normal for this product?**

Yes. OraQuick® ADVANCE™ is a rapid screening test for antibodies to both HIV-1 and HIV2, which can be used at the point of care with oral fluid, finger stick and venipuncture whole blood and plasma samples. All screening tests, whether used at the point of care or in the laboratory, will generate a certain percentage of false positive results. Consequently, all specimens that test positive for HIV with a screening test must be confirmed by additional testing using approved methods. The recent media stories concern a number of specific sites in San Francisco and New York City, and the L.A. Gay and Lesbian Center where the reported levels of false positive results while using OraQuick® ADVANCE™ with oral fluid were higher than expected based on the previously established performance for the product.

- 2. How accurate is the OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test supposed to be?**

Based on clinical data collected by OraSure, OraQuick® ADVANCE™ has a specificity approved by the U.S. Food and Drug Administration (FDA) of 99.8% for oral fluid. As a result, the test can be expected to achieve a specificity under normal circumstances in the general population ranging from 99.6% to 99.9%, which represents a 95% confidence interval for the FDA-approved product.

Specificity is a measure of accuracy that indicates the percentage of tests that will correctly show a negative result when the patient is not infected. For all screening tests, a small percentage of tests conducted will generate a positive result when the patient is not infected. This occurrence is commonly referred to as a false positive result.

In November 2005, the Centers for Disease Control and Prevention (CDC) presented preliminary post-market surveillance data from the use of OraQuick® ADVANCE™ at 347 sites across the U.S. According to the CDC data, a total of 17,220 oral fluid tests were performed with an indicated specificity of 99.8%, which is consistent with the FDA-approved label claims for this product. The full presentation can be found on the web at:

http://www.fda.gov/ohrms/dockets/ac/05/slides/5-4190S1_8_files/frame.htm

3. What exactly has been reported at the clinics with respect to false positive results?

Recently, some specific sites in San Francisco and New York City and the L.A. Gay and Lesbian Center reported levels of false positive results while using OraQuick[®] ADVANCE[™] with oral fluid that are higher than expected based on the previously established performance for the product. Other sites within these same regions have reported performance within the product claims.

4. Is it true that some of these sites have stopped using OraQuick[®] ADVANCE[™] as a screening test for HIV?

In all cases, these customers continue to use OraQuick[®] ADVANCE[™] with either oral fluid or whole blood as their rapid test for HIV screening.

5. What has the Company done in response to the reports of false positives?

Immediately after receiving these reports, the Company commenced a scientific and systematic evaluation of each situation. The Company is closely working with the affected customers, healthcare officials and government agencies, including The Centers for Disease Control and Prevention ("CDC") and the U.S. Food and Drug Administration ("FDA") and is providing information and updates regarding its evaluation on a regular basis to all such parties. The evaluation includes the collection of test data, an assessment of test procedures, specimen collection and other clinical variables that could affect test results at the sites. The Company is also conducting a thorough review of its manufacturing processes and all related variables that may affect product performance and quality, and has been contacting its customers throughout the country to determine if they are experiencing any unexpected results or issues with regard to the performance and procedures associated with the test.

6. What has the Company learned so far as a result of the evaluations?

The Company continues to make good progress with its evaluation. The following is an update on some of the information generated as of January 10, 2006.

- The Company has contacted certain state and city health departments, HIV/AIDS service organizations and other public health agencies in 35 states. Of this total, agencies in eight states, which include the specific sites that have recently reported the unexpected test results, have provided aggregate test data to the Company. The data indicates that approximately 112,000 oral fluid tests were performed in these states during 2005, with a calculated aggregate specificity of 99.8%. (It must be emphasized that these figures reflect only data reported to the Company by the agencies contacted in these states and are based on estimates of the total number of oral fluid tests performed. This data has not been audited and may not reflect the results of all oral fluid HIV testing in each of these states.) Agencies in many of the other 27 states contacted, from which the Company has not received quantitative performance data, have generally indicated that they are satisfied with the overall performance of the test and have not experienced an unusual level of false positive results. Based on the data and information collected as

of January 10, 2006, the Company believes that the OraQuick® *ADVANCE*™ test, when used with oral fluid, continues to perform overall as expected and in a manner consistent with its FDA-approved label claims.

- The Company has conducted an analysis into the possible relationship between product performance and particular lots of product used at the customer sites that reported unexpected results. So far, the Company has found no correlation between the reported false positive issues at these sites and particular lots of the OraQuick® *ADVANCE*™ test. For example, within two regions that had certain sites experiencing higher false positive rates, the same lot of product was used over the same time period by other sites within that region and in other parts of the country and demonstrated performance consistent with its FDA-approved label claims.
- The Company has obtained monthly test data from sites within the regions that reported higher levels of false positive results. After reviewing the data for the testing period of September through November 2005, the Company found that only a few sites within those regions experienced specificity that was significantly lower than that observed at the other sites in those regions. Excluding the monthly test results from these few sites, the aggregate specificity for the remaining sites in these regions was consistent with the product's expected performance and FDA-approved labeling. These findings are suggestive that a site-dependent factor may be playing a role in the lower specificity observed at these sites and the Company is continuing to evaluate this possibility as part of its evaluation. These factors could include potential interfering factors, sample collection and testing procedures, or patient specific variables.
- The Company is performing several experimental field studies involving the use of the OraQuick® *ADVANCE*™ test in oral fluid. These studies will focus on a number of variables that could affect test performance, including lot variation, shelf life, specimen collection and various site-specific factors observed by the Company during its data collection process.

7. Have unaffected customers been notified of the issue?

The Company has been contacting its customers throughout the country to determine if they are experiencing any unexpected results or issues with regard to the performance and procedures associated with the test, to answer any questions they may have, and to reinforce the Company's commitment to quality and customer satisfaction.

8. Who should customers contact if they experience any issues, or how can they find out more information?

Customers who experience any issues with the performance of the OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test or have any questions or concerns can contact the OraSure Technologies Customer Care Department at 1-800-ORASURE (1-800-672-7873).

Important Information Regarding Answers to Frequently Asked Questions

The information provided above contains certain forward-looking statements, including with respect to technical investigations, product performance, and product use and sales. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and other new products or technology; ability to fund research and development and other projects and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain, and timing of obtaining, necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability, patent infringement, and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2004, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements or the responses to the foregoing Frequently Asked Questions..