

## Standard Best Practices

**Satellite Conference and Live Webcast**  
**Thursday, August 23, 2012**  
**10:30 a.m. – 12:00 p.m. Central Time**

Produced by the Alabama Department of Public Health  
 Video Communications and Distance Learning Division

## Faculty

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**Account Manager**  
**OraSure Technologies**

### Minimum Standards of Testing

- Ensure proper Package Insert protocols are followed:
  - Always read the Package Insert before testing
  - Do not touch the flat pad
  - Do not block the 2 holes on the back of the test
  - Do not over collect the specimen

### Minimum Standards of Testing

- Do not move the test stand during test development
- Ensure adequate lighting is available
- Always utilize universal precautions
- Testers should be trained prior to conducting testing

### Oral Fluid Collection Protocol

**Wait 15 min after intake of any liquids or solids before collecting.**

**Wait 30 min after use of oral care products before collecting specimen.**

*Technical Services Bulletin*  
 Oral Fluid Collection Protocol with OraQuick ADVANCE<sup>®</sup> Rapid HIV-1/2 Antibody Test

**ORAL FLUID PROCEDURES**  
 This bulletin is intended to clarify the oral fluid specimen collection method, as listed on pages 1 and 7 of the OraQuick ADVANCE<sup>®</sup> product insert. Proper specimen collection is an important step for testing procedure. To correctly complete for oral fluid testing, the patient must be able to reach their upper and lower gums. There are several dental products that may not allow for adequate access to the gum line. These products are 1) dentures that completely cover the gum line or dent braces that cover the gum line. OraSure suggests that any dental product that inhibits or obstructs the gum line be removed prior to oral fluid collection. It is at the discretion of the site personnel to determine if the dental product inhibits the proper collection of oral fluid specimen.

**STEP 1: COLLECT**  
 Ensure prior to testing that the subject has not had anything to eat, drink or had cleaned gum for at least 15 minutes prior to testing if they have used any oral care products.

1. Have the person being tested remove the Device from its pouch. DO NOT allow the person to touch the Flat Pad (see picture 1A). Check to make sure that an Absorbent Packet is included with the Device (see picture 2A). If no Absorbent Packet is present, discard the Device and obtain a new Device for testing.

2. Place the person to place the Flat Pad above the teeth against the inner gums. Direct the person to gently rock completely around the outer gums, both upper and lower, one time around only using the Flat Pad (see pictures 3A and 4A). DO NOT allow the person to reach the rest of the mouth, the inside of the cheek, the tongue, or to wash the gums more than one time. DO NOT leave the mouth in the mouth, before or after performing the swabbing process. NOTE: One side of the Flat Pad may be used on this procedure, but be sure the person only swabs once around the gums.

For further inquiries, please contact OraSure Technologies Customer Care at 1-800-ORASURE (648-623-2672) or visit our website at [www.ora.com](http://www.ora.com).

*Technical Bulletin*  
 08-05-008

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### Oral Fluid Specimen Collection

**Simple collection instructions. Be sure to collect once around the upper and lower outer gums.**

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2. Place the person to place the Flat Pad above the teeth against the inner gums. Direct the person to gently rock completely around the outer gums, both upper and lower, one time around only using the Flat Pad (see pictures 3A and 4A). DO NOT allow the person to reach the rest of the mouth, the inside of the cheek, the tongue, or to wash the gums more than one time. DO NOT leave the mouth in the mouth, before or after performing the swabbing process. NOTE: One side of the Flat Pad may be used on this procedure, but be sure the person only swabs once around the gums.

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### **OraSure Efforts Towards Optimum Customer Quality**

- OraSure maintains a vast surveillance monitoring system established at sites strategically selected around the United States who perform oral fluid testing
  - This data is utilized to monitor product performance so that OraSure can respond appropriately

### **OraSure Efforts Towards Optimum Customer Quality**

- Current data over the past year includes 80,241 tests with a specificity of 99.91% with a 95% confidence interval of 99.89% - 99.93%

### **OraSure Efforts Towards Optimum Customer Quality**

- OraSure investigates and works to resolve all reported discordant results
  - It is important to report any incident as soon as possible

### **OraSure Product Improvement and Development**

- In early 2009 OraSure released an enhanced version of the OraQuick HIV test with improved oral fluid specificity and increased shelf life
  - Shelf life has now been extended to 30 months

### **OraSure Product Improvement and Development**

- OraSure maintains a strong pipeline of product development in point-of-care testing for infectious disease
  - This includes work on rapid HIV tests with increased sensitivity and specificity as well as detection of new markers, both antigens and antibodies

### **Contact Information**

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