#### **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**

Amy Malik
Account Manager
OraSure Technologies

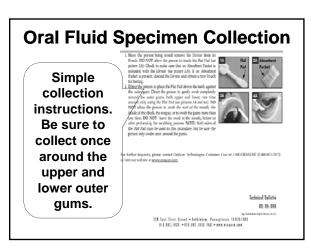
#### **Minimum Standards of Testing**

- 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 Technical Services Bulletin after intake of Oral Fluid Collection Protocol with any liquids or OraQuick ADVANCE Rapid HIV-1/2 Antihody Test solids before collecting. Wait 30 min after use of oral care products before collecting specimen.



### 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-ofcare 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**

Amy Malik
Account Manager
OraSure Technologies

Cell: 610 - 442 - 6976 Email: amalik@orasure.com