The Future of Laboratory Medicine
Simple Testing, Diverse Sites
February 14, 2007

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Division of Laboratory Systems
Centers for Disease Control and Prevention
Plan for CLIAC Meetings

• Spring 2006 – Enhancing Connectivity Between Public Health and Clinical Laboratories

• Fall 2006 – Future of Health Laboratory Practice: Challenges to laboratories performing “complex” testing in “traditional” locations

• Spring 2007 – Future of Health Laboratory Practice: Challenges to Laboratories performing “simple” testing in diverse sites
Spring 2006
Enhancing Connectivity Between Public Health and Clinical Laboratories

• Role of the public health laboratory
  ▶ Scope of services
  ▶ Customers
  ▶ Connectivity
  ▶ Preparedness

• CLIAC recommended formation of a workgroup on the impact of rapid and molecular tests for infectious disease agents on public health
Fall 2006
Future of Health Laboratory Practice

- Challenges to laboratories performing “complex” testing in “traditional” locations
  - Future directions in laboratory technology
  - Interfaces between the laboratory and clinician: information technology and electronic medical records
  - Future of the laboratory workforce
Challenges to laboratories performing “simple” testing in diverse locations

- Evolution of point-of-care testing
- Impact of the MMWR publication of Good Laboratory Practices for Waived Testing Sites
- Workgroup Report: The Impact of Rapid and Molecular Tests for Infectious Disease Agents on Public Health
- Use and evaluation of rapid HIV testing
### Changes in Laboratory Demographics 1993-2006

#### Total Laboratories by Certificate Type

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<tbody>
<tr>
<td>Total # Labs</td>
<td>152,250</td>
<td>150,229</td>
<td>170,996</td>
<td>188,741</td>
<td>201,549</td>
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<td>Total # POLs</td>
<td>90,800</td>
<td>88,028</td>
<td>95,879</td>
<td>105,914</td>
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#### Total Laboratories by Certificate type

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<tbody>
<tr>
<td>Waiver</td>
<td>67,294</td>
<td>74,455</td>
<td>88,730</td>
<td>113,445</td>
<td>114,680</td>
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<td>PPM</td>
<td>16,443</td>
<td>28,931</td>
<td>36,850</td>
<td>39,209</td>
<td>38,051</td>
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#### POLs by Certificate Type

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<tr>
<td>Waiver</td>
<td>NA</td>
<td>32,497</td>
<td>42,793</td>
<td>52,632</td>
<td>55,219</td>
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<td>25,987</td>
<td>30,959</td>
<td>32,388</td>
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What are the questions we should be asking and what can you help us learn about simple laboratory testing in diverse and non traditional sites?

• Are the current laboratory practices adequate to meet the intended use and provide the desired outcomes?

• What are the metrics and methods we should be using to determine whether laboratory practices are meeting the public health and clinical care needs?

• What are the “good laboratory practices” that seem to assure high quality services in these settings?

• Are there gaps in our policies that should be addressed to meet the special needs and improve laboratory testing in these settings?
What are the public health and clinical care implications for testing in diverse and nontraditional sites?

Possible downsides –
- Gaps in reporting?
- Consumer confusion about test results and health implication?

Possible benefits -
- Improved access to testing services?
- Better quality?
- Improved collaboration between public and private laboratories?
CLI AC Agenda
February 14, 2007

• Dr. Paula Santrach
  Current and Future Applications for POCT

• Ms. Sharon Granade
  CDC Report on Dissemination/Marketing of MMWR Recommendations

• Ms. Karen Breckenridge
  APHL Report on Status of Waived Testing Instructional Materials

• Dr. Christine Bean
  New Hampshire Training Based on MMWR Publication
• Dr. Barbara Robinson-Dunn
  Workgroup Report: The Impact of Rapid and Molecular Tests for Infectious Disease Agents on Public Health

• Dr. Devery Howerton
  Summary of Findings from the Model Performance Evaluation Program for Rapid HIV Testing

• Mr. Duncan MacKellar
  Use of Rapid HIV Testing in the Public Health Sector

• Dr. Laura Bogart
  Use of Rapid HIV Testing in the Private Sector
Questions for CLI AC Consideration

For simple testing in diverse sites:

- What are some of the challenges we can expect?

- Where can we expect gaps in regulations, policies, standards, and guidelines?

- What innovations might address these gaps?

- What else might be needed?
Thank you
Questions/ Comments