



# **The Future of Laboratory Medicine**

## **Simple Testing, Diverse Sites**

**February 14, 2007**

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# 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



## Spring 2007 Future of Health Laboratory Practice



- 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



	1993	1997	2001	2005	2006
<b>Total # Labs</b>	152,250	150,229	170,996	188,741	201,549
<b>Total # POLs</b>	90,800	88,028	95,879	105,914	108,011

<b>Total Laboratories by Certificate type</b>					
	1993	1997	2001	2005	2006
<b>Waiver</b>	67,294	74,455	88,730	113,445	114,680
<b>PPM</b>	16,443	28,931	36,850	39,209	38,051

<b>POLs by Certificate Type</b>					
	1993	1997	2001	2005	2006
<b>Waiver</b>	NA	32,497	42,793	52,632	55,219
<b>PPM</b>	NA	25,987	30,959	32,388	33,145



## 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?



# CLIAC 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



# CLIAC Agenda

## February 15, 2007



- 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 CLIAC 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**