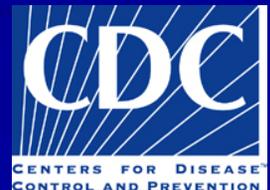


Introduction/Overview

Current Research Activities

CLIAC Meeting
February 4, 2009

Devery Howerton, PhD
Chief, Laboratory Practice Evaluation and Genomics Branch
Division of Laboratory Systems, CDC



Current Focus:

Filling Gaps and Strengthening Systems

- What basic information is needed to better understand where quality improvement efforts need to be focused?
- What are the highest priority policy considerations?
- What approaches are most effective in building the needed evidence base for practice standards and guidelines?
- How can the pre- and post-analytic interface be evaluated and improved?
- What impact is new technology having on the field – both complex testing (e.g., genetic testing) and simplified testing (waived testing)?

Current Focus:

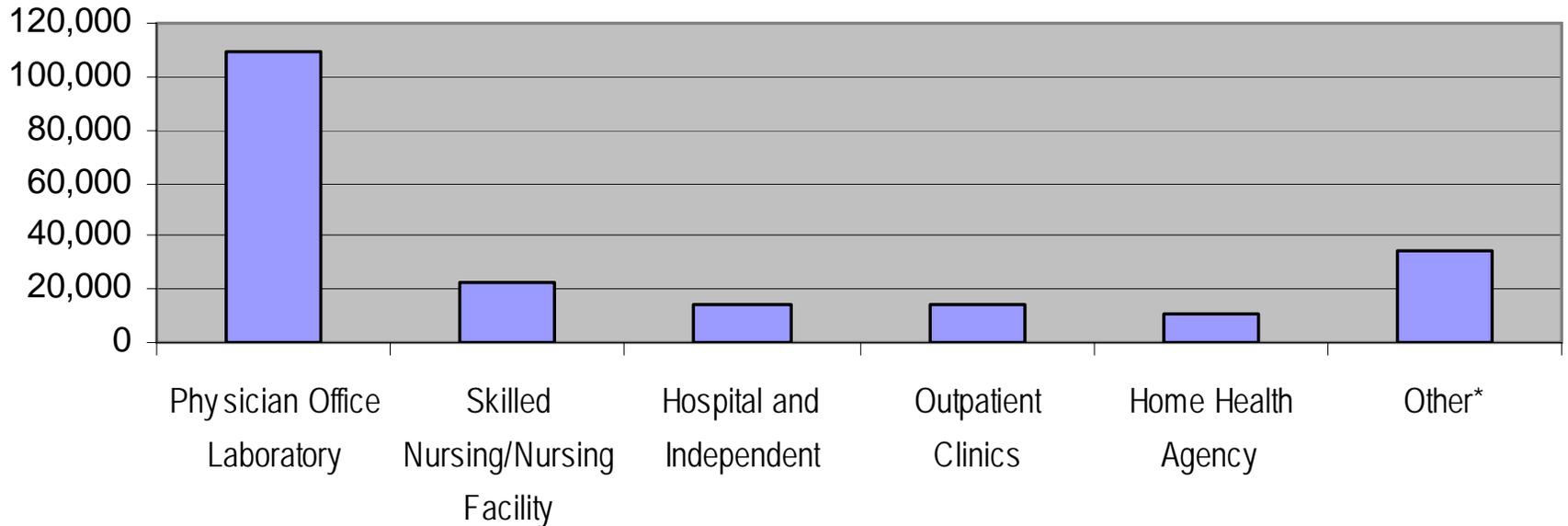
Filling Gaps and Strengthening Systems

- **Basic information: lab demographics, diffusion of rapid testing (influenza)**
- **Lab path of workflow:**
 - **Analytic: reference materials, PT data**
 - **Pre- and post-analytic:**
 - **Performance measurement and improvement**
 - **Evidence base for best practices**
 - **Clinical decision support**
- **Education and guidance:**
 - **e-training for clinicians about genetic testing**
 - **Practice guidelines for genetic testing laboratories**

Projects FY '2008...

- Defining Best Practices in Laboratory Medicine
- Evidence-Based Laboratory Medicine: Quality/Performance Measure Evaluation
- The Clinical Laboratory Report as a Decision-Support Tool
- Evaluation of the Use of Rapid Testing for Influenza in Outpatient Medical Settings
- Developing an Agenda for Laboratory Practice Research Based on the 2007 Institute

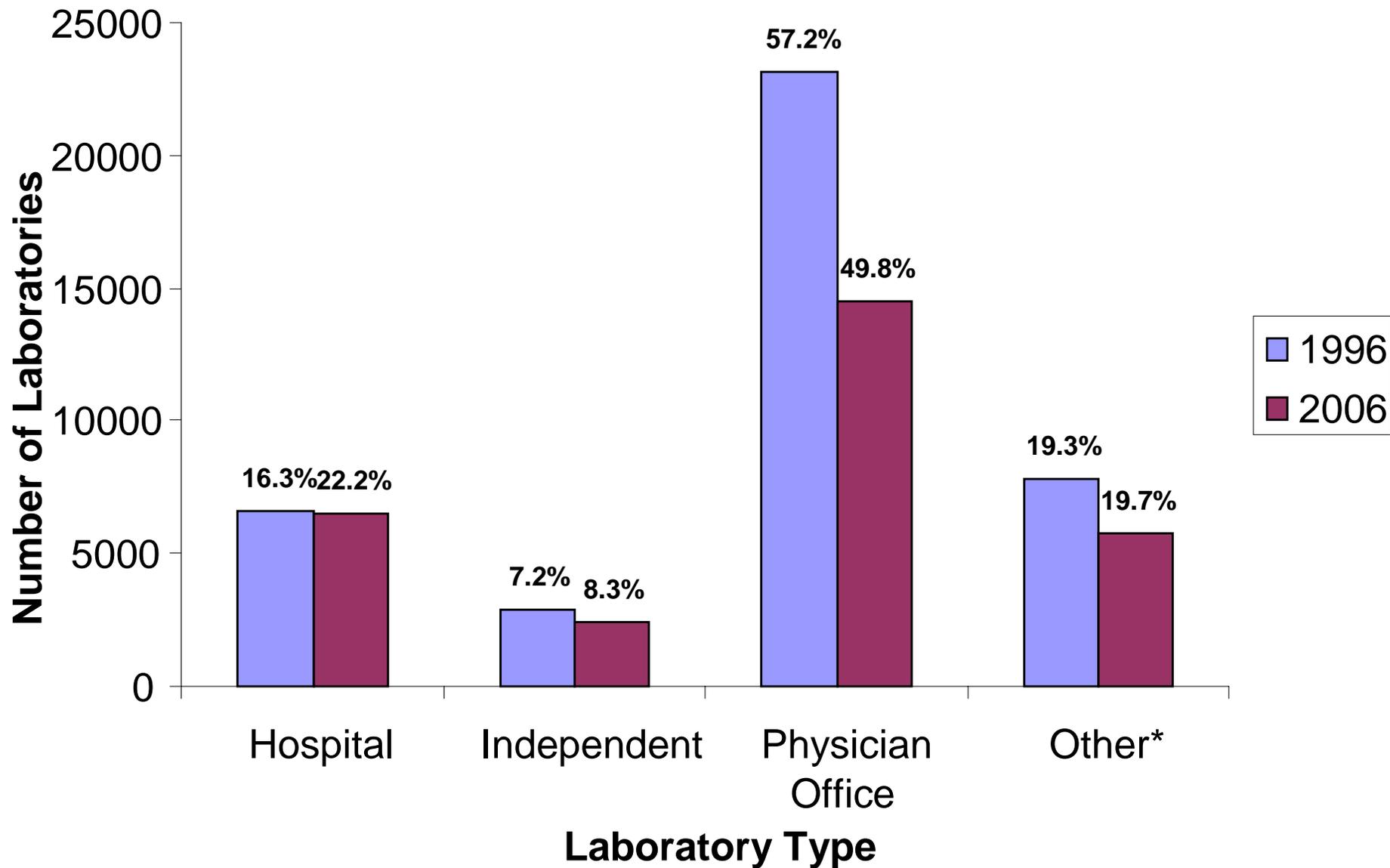
U.S. Laboratory Demographics



- **205,286 CLIA-certified laboratories**
- **333,000 laboratory personnel**
- **8 billion tests/year**
- **\$48.5 billion/year in laboratory revenues**

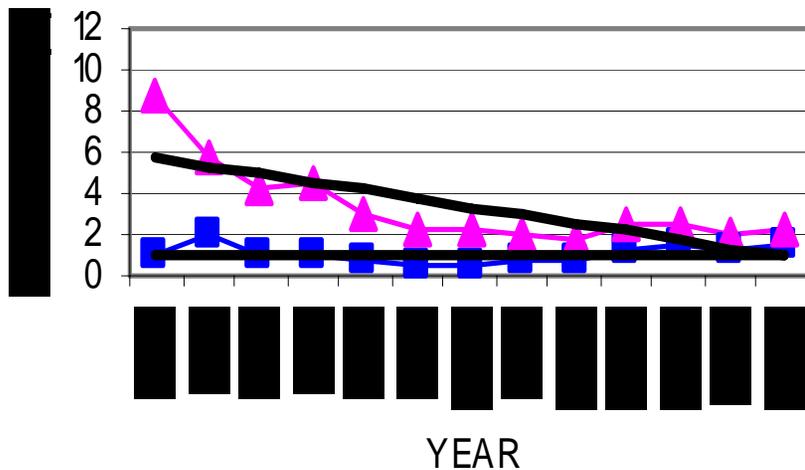
* Public health laboratories, insurance, pharmacy, tissue bank/repositories, blood banks, ambulance and mobile units, industrial, health fair, ancillary test sites, school/student health service, other not specified.

Distribution of Laboratory Types Participating in PT, 1996 and 2006

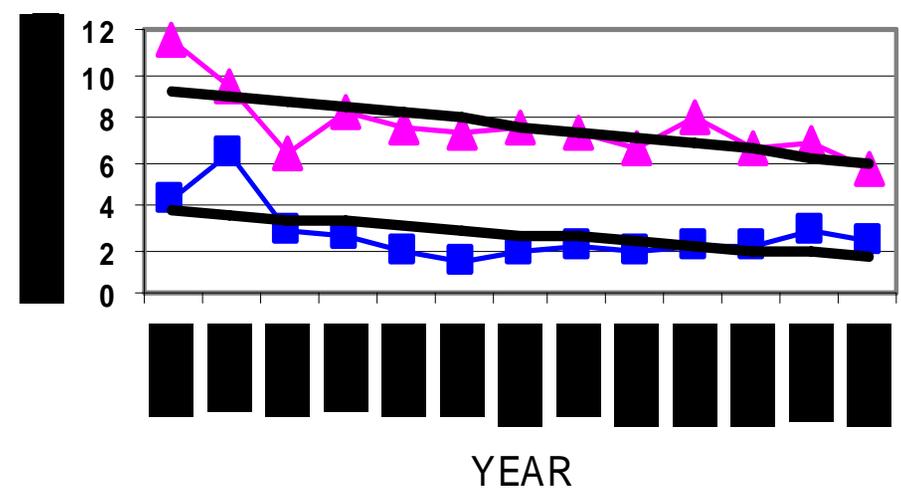


PT Performance in US Laboratories, 1994-2006*

Potassium (K+)



Glucose



Manuscript submitted, data from CMS OSCAR and PT databases

Promoting Quality in Genetics Testing

Promoting a
Framework for
Quality



**International
Standards** 
ISO, OECD, CLSI

SACGHS



U. S. Department of Health
and Human Services

Promoting
Analytic Validity



Promoting Appropriate
Test Use and
Professional Competency



Evidence-Based Laboratory Medicine: Quality/Performance Measure Evaluation

Question: What evidence-based laboratory medicine quality/performance measures associated with pre- and post-analytical processes and consistent with national health care priorities can be used to improve patient outcomes and public health?

- Newborn Screening – TX State Dept of Health
- Pathology and patient safety - Multi-site measurement assessment – Univ of Colorado
- **Chronic kidney disease – Kaiser Permanente Center for Health Research**

Evidence-Based Laboratory Medicine Best Practices

Systematic Review Methods
CDC Review Team with guidance
from independent **Expert Panels**
screen, abstract synthesize
and summarize evidence

**Evidence
Summaries**

Evaluation Methods
Independent **Expert Panelists**
rate evidence using pre-specified
criteria

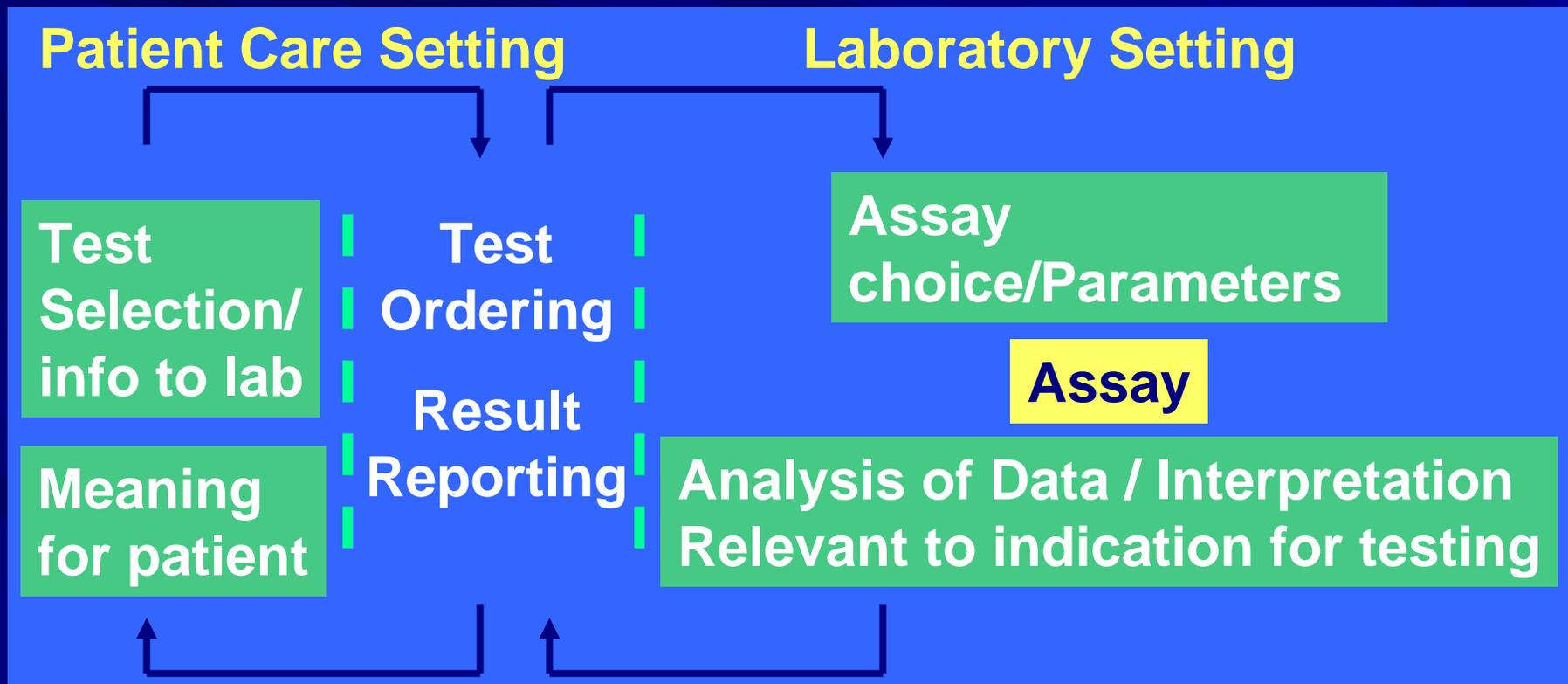
**Consensus
Ratings**

Evidence-Based Recommendations
Recommending body (**LMBP
Workgroup**) makes best practice
recommendations based on evaluations

Clinical Decision Support

- Effectively manage knowledge to promote
 - Patient benefits
 - Cost effectiveness of testing services
 - Informed decision making

Application of Expert Systems



Presentations

- **Evidence-Based Performance Measures in Chronic Kidney Disease**
 - David Smith, RPh, PhD, Kaiser Permanente Center for Health Research
- **Evidence-Based Best Practices in Laboratory Medicine: Evidence Evaluation Methods**
 - Ed Liebow, PhD, Battelle Centers for Public Health Research and Evaluation
- **Clinical Decision Making: Promoting Appropriate Reporting and Understanding of Molecular Genetic Test Results**
 - Ira Lubin, PhD, FACMG, Geneticist, Centers for Disease Control and Prevention
 - Lee Hilborne, MD, MPH, FASCP, DLM(ASCP), Deputy Director, Global Health, Rand Center for Domestic and International Security



Questions to Consider: Current Focus

- How can the work presented be leveraged to address essential needs of the laboratory medicine community?
- What suggestions do you have regarding the approach, its capacity to achieve the outcomes sought?
- Where do you think this work can lead in the future?
- Who might be key partners in moving the work forward?