



# **CDC Update**

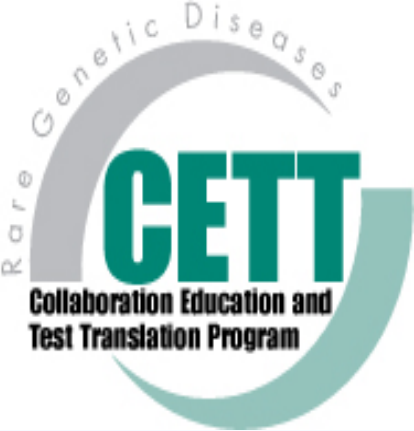
## **September 20, 2006**

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**Division of Laboratory Systems**  
**CDC**

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# Topic Areas

- Progress in Genetics
- 2007 Conference - "Managing for Better Health"
- Research – "Defining Best Practices in Laboratory Medicine"
  - ❖ **Structure - Where are we now and where are we going?**
  - ❖ **Process - How can we identify and implement Best Practices?**
  - ❖ **Outcome -Can we make PT more effective?**
- Workgroup – Impact of Rapid and Molecular Tests for Infectious Diseases on Public Health



# Collaboration, Education, and Test Translation

**Purpose:** Facilitate translation of genetic tests from research to practice

**Process:** Collaboration - research laboratory, clinician involved in the study of the disease, a CLIA laboratory, patient advocacy group

**1<sup>st</sup> Test:** July 21 - Cornelia de Lange Syndrome University of Chicago

**Cost:** \$2400 **Turn-around time:** 10 weeks

**Link to information:**

<http://genes.uchicago.edu/DiagnosticTests.html>

**Other tests in Fall 2006:**

- ❖ *ATP7B* sequencing for Wilson disease
- ❖ *GP1BB* sequencing for Bernard-Soulier syndrome

**CETT Site:** <http://www.cettprogram.org/>

**Workgroup:**  
**Quality, Access, and Sustainability of Biochemical Genetic Testing**  
**October 6-7, 2006, Atlanta, GA**

**Purpose:** Explore CETT program for biochemical genetic tests

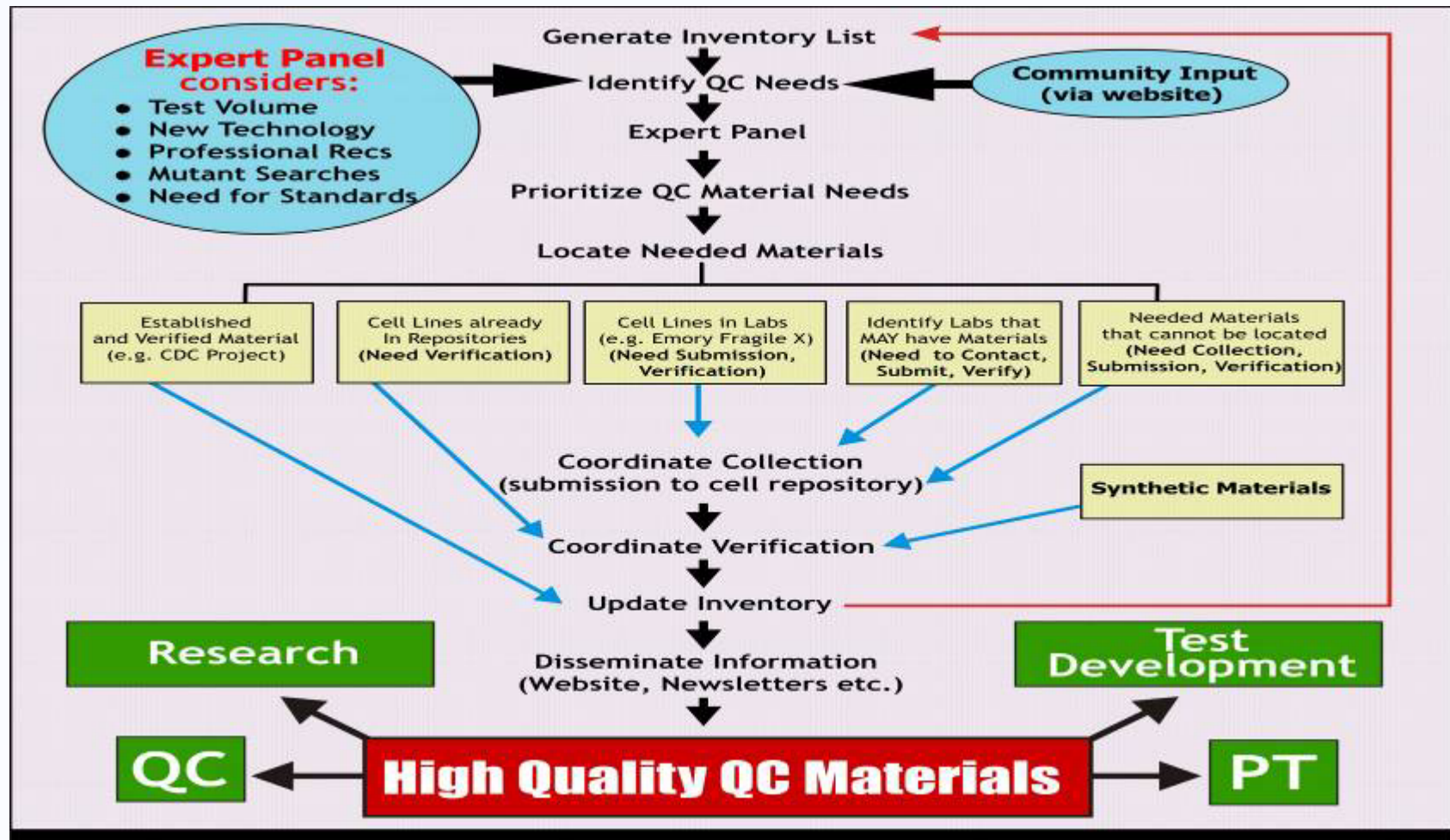
**Concerns:**

- Tests from limited number of laboratories
- Laboratories discontinuing testing services
- No process to move tests from the research to practice
- Materials for QC and PT are often not available
- Collaboration - biochemical and molecular testing laboratories
- Reimbursement and liability may restrict services, such as prenatal diagnosis
- Testing service information often not readily accessible.
- Shortage of trained personnel and training programs.



# GTQCC

## Genetic Testing Quality Control Materials Program



## Recent Success

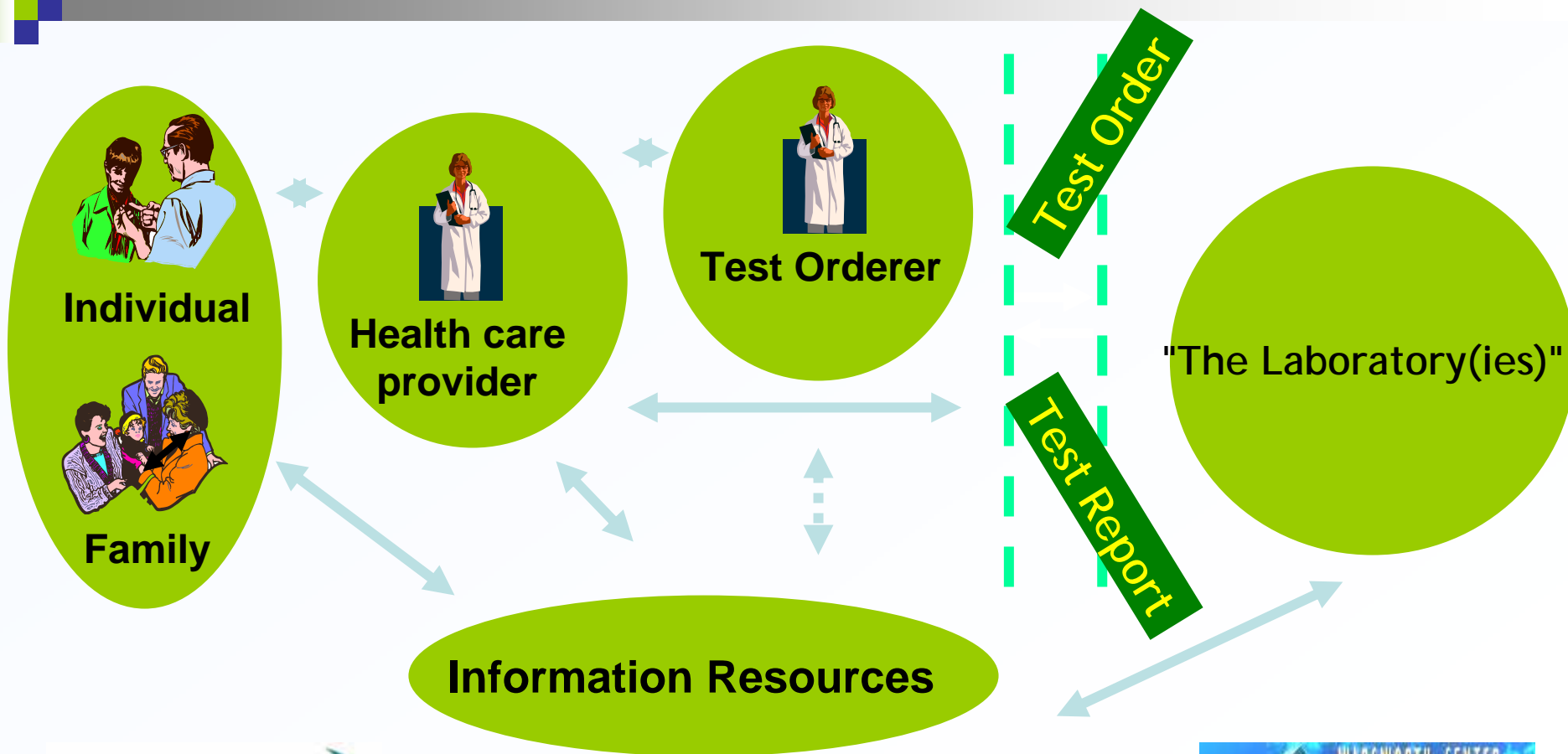
- Verified 14 Huntington Disease Cell Lines
- Verified Ashkenazi Jewish panel of 27 variants
- Coriell cell lines typed for Pharmacogenetic loci

Coming soon

- Fragile X

# Deriving Actionable Information from Testing

## Focus: Genetic Testing



# Oversight of Genetic Testing

## US Issues

- Analytical validity
- Clinical validity
- Home brew testing
- Internet (Tests to Public)
- Informed consent
- Education: Users of Lab Services
- Communication
- Use of Residual Specimen
- Balancing access and quality





# Oversight of Genetic Testing

## International

Organization for Economic Cooperation and Development (OECD)  
“Guidelines for Best Practices in Quality Assurance for  
Molecular Genetic Testing”

- 2002 Survey of 18 countries
- Principals and Best Practices
  - ❖ **General**
  - ❖ **Quality Assurance**
  - ❖ **PT**
  - ❖ **Result Reporting**
  - ❖ **Education and training of laboratory personnel**



<http://www.oecd.org/sti/biotechnology/qualityassurance>



# 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health



**Purpose:** To identify ways to enhance the management of laboratory practices and use of laboratory services to promote better health.

## **Assumptions:**

- Current practices cannot cope with anticipated changes in technology, patient care options, knowledge management needs, and resource limits
- Laboratory services are essential to patient care and public health and appropriate and effective use of these services must be a high health care priority.
- Enhancements in informatics capability could allow the laboratory to play a major role in the coordination and continuity of care.

## **Topic Areas**

Management systems, Informatics, Technology

Integrated laboratory services, Customer expectations

# 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health

## For Each Topic Area

### Key Questions

- What are the major changes that have occurred in the past 5 years or are expected to occur in the next 5 years?
- What major changes need to occur in the next 5 years to enhance laboratory services?
- What are the expected benefits and costs of laboratory services if these changes do occur?

### Workgroup Discussion

- What are the major impediments, including policy issues and barriers of effectiveness, to implementing needed changes?
- Who should be responsible for assuring that promising changes are implemented?
- What resources would be required to make these changes within institutions, regionally, and nationally?

# 2007 Institute on Critical Issues in Health Laboratory Practice: Managing for Better Health

**Location of conference – Atlanta**

**Date and Time - ?**

**Next Steps – Form Steering Committee and select  
Workgroup Leaders**

## **Structure of the Conference**

- **Opening and Closing sessions broadcast over internet.**
- **Workgroup sessions recorded, but not broadcast**
- **Conference proceedings published and posted on the CDC web-site**

# Defining Best Practices in Laboratory Medicine

## **Report on Status of Laboratory Medicine**

- **Scope and magnitude of the field**
- **Customers of laboratory services**
- **Factors affecting the delivery and quality of services**
- **Impact of regulation and accreditation on the field**
- **Common practices, performance measures**
- **Workforce trends**
- **Expectations for the Future**

# Defining Best Practices in Laboratory Medicine

## Developing a Process for Identifying Best Practices

- Form an Expert Workgroup
- Define “Best Practice”
- Establish criteria for selecting candidate practices
- Solicit candidate Best Practices in target area
  - ❖ POCT for Infectious Disease
- Conduct pilot test of process
- Disseminate findings

# Defining Best Practices in Laboratory Medicine

## Evaluation of Proficiency Testing Services

- Form an Expert Workgroup
- Establish set of goals for PT programs
  - ❖ Do US Programs meet quality improvement goals?
  - ❖ Do US Programs meet regulatory goals?
  - ❖ Do US Programs meet education goals?
- How could PT programs enhance their value to laboratories?
- Are PT programs keeping pace with changing technology?
- Would conformance to an international standard enhance PT program usefulness?
- Disseminate findings





**Workgroup:**  
**Impact of Rapid and Molecular Tests for Infectious Diseases  
on Public Health**  
**November 2, 2006, Atlanta, GA**

**Purpose:** Discuss concerns raised during February 2006  
CLIAC Meeting

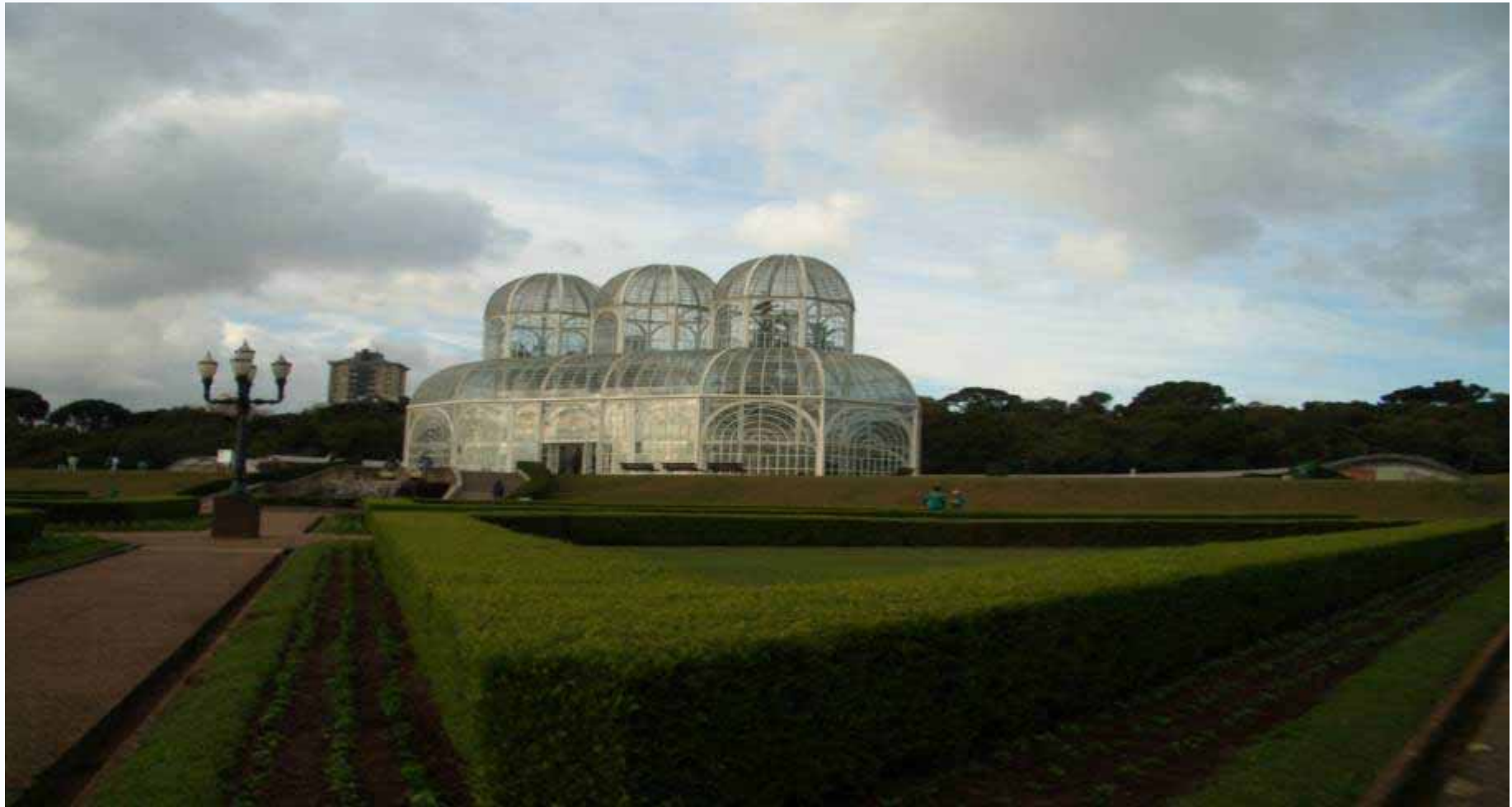
**Concerns:**

- Need for confirmatory testing for some screening tests
- Specimen or cultures not available for confirmatory testing or epidemiologic surveillance
- PH epidemiology data missing for outbreak investigation and disease surveillance
- Test sites unaware of PH reporting requirements – State to State variation
- Testing service information often not readily accessible



# Thank you

## Questions/Comments



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