

# Development of Genetic Testing Quality Control (GTQC) Program

D. Joe Boone, Ph.D

International Symposium on Reference Materials

for Genetic Testing

Geel, Belgium

November 30, 2005



# Goals

- Describe research efforts to address the need for positive control materials
- Describe three previous conferences aimed at making materials available for QC
- Introduce the GTQC Program
- Encourage your participation in the process

# Background

- **Recommendations for QA for Molecular Genetic Tests** - CDC Contract DynCorp Health Research Services - 1999

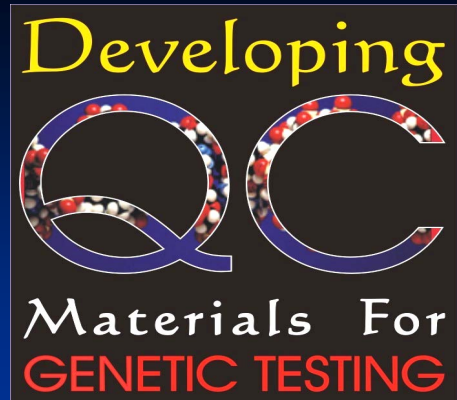
<http://www.phppo.cdc.gov/dls/pdf/genetics/dyncor.pdf>

- **Process to collect positive samples and establish stably transformed cell lines**

CDC Contract Duke University - 2000

- **Genetic engineering to develop positive samples**

CDC Contract UCLA - 2000



## QC Materials Conferences

- Based on successful research leading to a reliable process for collecting and validating cell lines
- September 15-16, 2003
- March 8, 2004
- November 9, 2004
- **Purpose:**  
To develop a sustainable process to collect, store, validate, and distribute materials at a reasonable cost

# QC Materials for Genetic Testing

- **Conference Organizers**

CDC, NIH, NIST

- **Participants**

Professional associations

Government agencies

Industry

Laboratories

Academic institutions

## QC I – September 2003

- Reviewed current and future needs for materials for genetic tests
- Reviewed research to produce materials suitable for positive QC for genetic tests
- Discussed ways to develop sustainable process to provide QC materials to genetic testing laboratories at a reasonable cost.

# QC Material Workgroups

- **Research** - Roger Lebo
- **Funding Coordination** - Joe Boone
- **Professional Guidance** - Dan Farkas
- **Oversight of QC Products** - Maria Chan
- **Validation of QC Materials** - Larry Silverman and Catherine O'Connell
- **Use of Cell Banks** - Jeanne Beck
- **QC Material Priorities** - Jean Amos Wilson
- **Material Contributors** - Sue Richards and Ben Roa

# QC II - March 8, 2004

## Contributors to success

- Federal leadership
- Public/Private partnership
- National QC Material Coordinator
- Expert Panel to support Coordinator
- Protocols for collection, validation and distribution
- Incentive program for contributions
- Website of resources
- Presentations and publications about materials development



# QCIII - November 9, 2004

- Coriell and other cell banks act as repositories and distributors of materials
- National QC Material Coordinator
  - Community Process
  - Defined Priorities
- Expert Panel to support Coordinator
- Protocols/Incentives for collection, validation and distribution of materials
- National and International Cooperation
- Communications and Website development

# Summary of Conference (1)

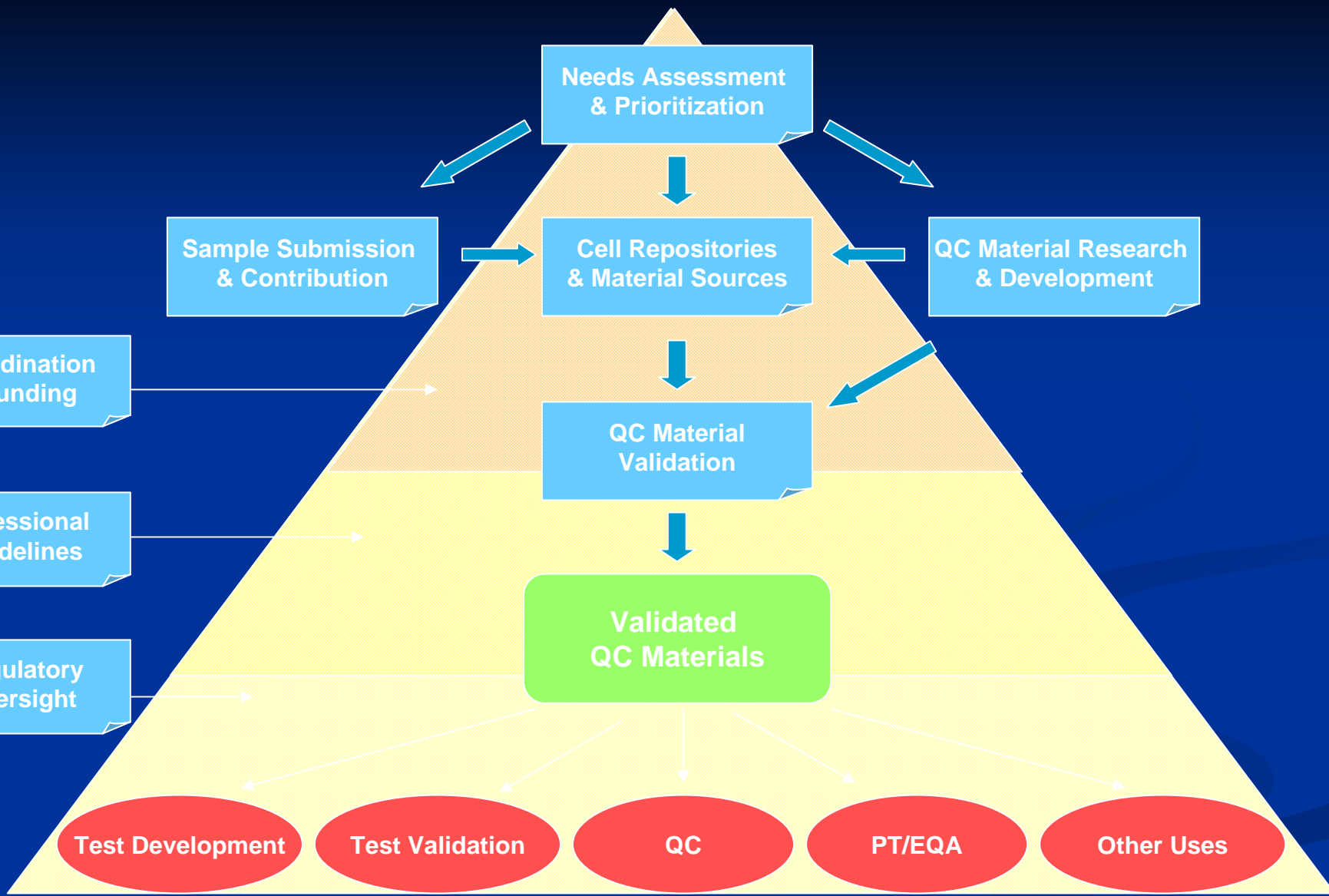
- **Materials can be obtained and made available at a reasonable cost**
- **A sustainable process**
  - **Facilitate research in QC material development**
  - **Develop better coordination of funding**
  - **Develop guidance on appropriate use of QC materials**
  - **Clarify regulatory requirements**

## Summary of Conference (2)

- **A sustainable process**
  - **Develop validation processes for QC materials**
  - **Develop processes to use existing cell banks as sources for materials**
  - **Develop a scheme to set priorities for materials**
  - **Develop network of contributors of materials**

# Potential Sources of Material

- Coriell
- CRMGEN
- NIST
- ATCC
- Biobanks
- Clinical specimens (residual blood and patient recollection)
- Research labs
- Industry/Material developers
- Other?



# Community Input is Needed!

- Ideas/needs
- Material donation
- Material verification
- Support



**The QC Material Coordinator Needs Your Help!**

Contact: [LKalman@cdc.gov](mailto:LKalman@cdc.gov)

