

Developing



Materials For GENETIC TESTING

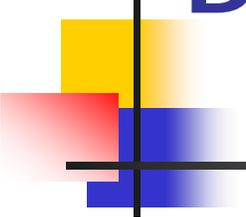
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<http://www.phppo.cdc.gov/dls/genetics>

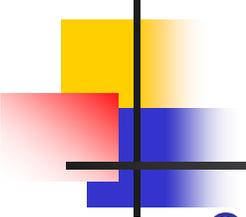
September 18, 2003





Developing a Sustainable Process

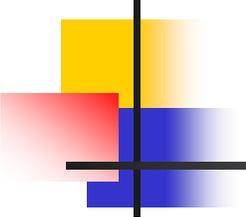
- How can QC Materials for genetic tests be developed or obtained?
- How can QC materials be validated?
- How can QC materials be collected and stored?
- How can QC materials be distributed at a reasonable cost ?



Conference Agenda

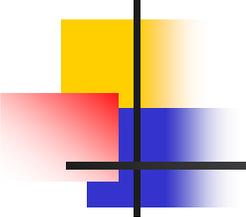
September 15-16, 2003

- Current QC Materials for Genetic Tests
- Research to Develop Materials for QC/PT
- Unmet and future needs?
- Applicability of research to address needs?
- Practical issues – validation and cost
- Bridging the gaps and sustaining a process



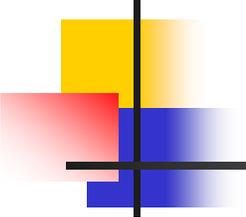
Applicability: Questions to Answer?

- Which unmet needs are easy to address?
- Which unmet needs are difficult to address?
- What are the strengths and weakness of the various methods to address needs?
- Would licensing pose a major or minor impediment to development and use of QC materials?



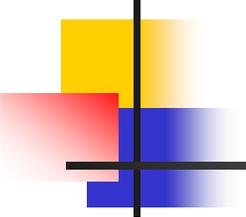
Practical Matters: Questions to Answer?

- Where are the areas of greatest need?
- How important is validation of QC materials?
- Can PT be used to validate QC materials?
- How can QC materials for rare diseases be obtained?
- What is an acceptable charge for QC materials?



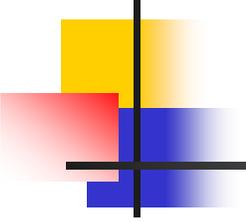
Gaps and Sustained Process: Questions to Answer?

- Who should play a role in development of QC materials?
- Who should play a role in validation of QC materials?
- Who should play a role in collection and storage of QC materials?
- Who should play a role in distribution of QC materials?
- Who should pay the bill for QC materials?



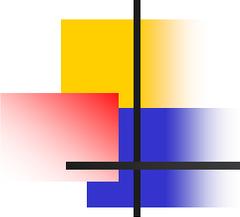
Summary of Conference #1

- Can make QC available at reasonable cost
- Need better collaboration among researchers
- Need better coordination of federal funding
- Professional guidance on appropriate QC
- Clarification of oversight in QC materials



Summary of Conference #2

- Defined validation process for QC materials
- Use existing cell banks to start
- Need scheme to set priorities for materials
- Need network of contributors of materials
- Better definition of roles of those interested in promoting QC for genetic tests



Next Steps

- Assigned a workgroup leader with responsibility for an item to develop
- Use leaders as steering committee to coordinate activities
- Next meeting in March 2004 – Perhaps around ACMG meeting?

