# CLIA EQC Option 4 Update

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# What is Option 4?

- Manufacturers may validate a quality control recommendation
- If FDA agrees that the validation shows that the recommendation is equivalent to traditional QC, then
- Labs may use the recommended QC instead of the CLIA-mandated QC
- Labs retain the responsibility to ensure this QC is appropriate for their facility

# Timeline

- AdvaMed proposed EQC option 4 in May, 2004
- EQC workshop at CLSI meeting in March, 2005
- CLSI committee established May, 2005
- Document for manufacturers expected March, 2007
- Document for labs being proposed

# Status of CLSI Manufacturers Document

- Conference call held
- Writing assignments with overwhelming response by all sectors
- Survey of combined comments to drive discussion
- Lots of agreement between sectors
- Document needs 2 parts:  regulatory requirements and end user requirements

# Manufacturer's Document Contents

- Platform and QC-recommendation neutral
- Up to manufacturer to decide to make recommendation
- Otherwise, "Follow your local, regional, or national requirements for Quality Control"
- Points to consider for designing quality into the device (wish list)

# Sections tentatively in document

- Characteristics of QC suggested to ensure quality of examination procedure
- Foundational concepts of validation for manufacturers to consider
- Validation studies suggested to increase confidence of regulators and end users (possibly accompanied by suggestions for statistical models)
- Examples of studies

# Sections tentatively in document

- Recommendations on content of product inserts and manuals

- Recommendations on content of data supplied to certifying bodies

# Next Steps

- Consensus on title
- Consensus on scope
- Consensus on document contents
- Writing assignments
- Development of consensus document