

# EP22 – Presentation of Manufacturer's Risk Information

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# Status Report: CLSI EP22 Guideline

Title: *Presentation of Manufacturer's Risk Mitigation Information for Users of in vitro Diagnostic Devices—Proposed Guideline*

- Project authorized: March 2005
- Project re-authorized: November 2007



# EP22 Subcommittee Members

- Greg Cooper, CLS, MHA, Chairholder
- Fred D. Lasky, PhD
- Francisca L. Lehr, MS, MT(ASCP)
- Dai J. Li, MD, PhD, FACB
- George S. Makowski, PhD, DABCC, FACB
- Adam Manasterski, PhD
- James H. Nichols, PhD, DABCC, FACB
- Curtis A. Parvin, PhD
- George M. Plummer



# Status: CLSI EP22 Guideline

- Two subcommittee drafts have been proposed and rejected
- Third draft submitted for subcommittee voting period ending 10 July 2008
- Focus is on information to be provided to user by the manufacturer; no mention of QC frequency

# Historical Perspective: CLSI EP22

- Originally intended to provide statistical and scientific guidance to allow manufacturers to make QC frequency recommendations in their labeling
  - No peer-reviewed science in clinical diagnostics currently exists that links risk assessment or reliability to frequency
  - Product labeling must have language that defers to regulatory requirements
  - Current recommendations such as “once per lot” not considered QC frequency by the FDA



# Scope: CLSI EP22

- Guidance to manufacturers
- Information for users of *in vitro* diagnostic devices regarding scope and effectiveness of design features intended to mitigate risk of device failure
  - Focus is on failure modes
    - How a failure manifests itself
    - How the risk mitigation feature works to prevent failure
  - Studies done to verify effectiveness of the design feature

# Means to Communicate Information

- Risk mitigation information can be supplied by manufacturers:
  - In the product insert
  - In the device manual
  - As a separate sheet
  - Via the internet
- Format of information
  - EP22 suggests a table with the following headers and information.

# Table Headers: CLSI EP22

- Device Feature or Recommended Action
- Targeted Failure Mode
- Description of How Feature or Recommended Action Performs Its Intended Function
- Known Limitations of Feature or Recommended Action
- Actions Required to Address Known Limitations
- Studies Performed to Verify Feature/Recommendation Achieves Intended Purpose

# Studies Performed

Proposed that manufacturer provide the following study information to demonstrate the robustness of the design feature or recommended action.

- Description
- Sample matrix tested
- Number of samples tested
- Reagents and calibrator lots tested
- Number of replicates
- Number and types of devices tested
- Location of testing
- Conditions of stress
- Statistical methods used
- Study results
- References



# Summary

- Provides a framework for sharing information with users
- Suggests key information to be shared with users to support local laboratory decisions about character and frequency of QC
- Should reduce or eliminate unsubstantiated QC recommendations

# Thank You

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