



AdvaMed CLIA Waiver Criteria Proposal

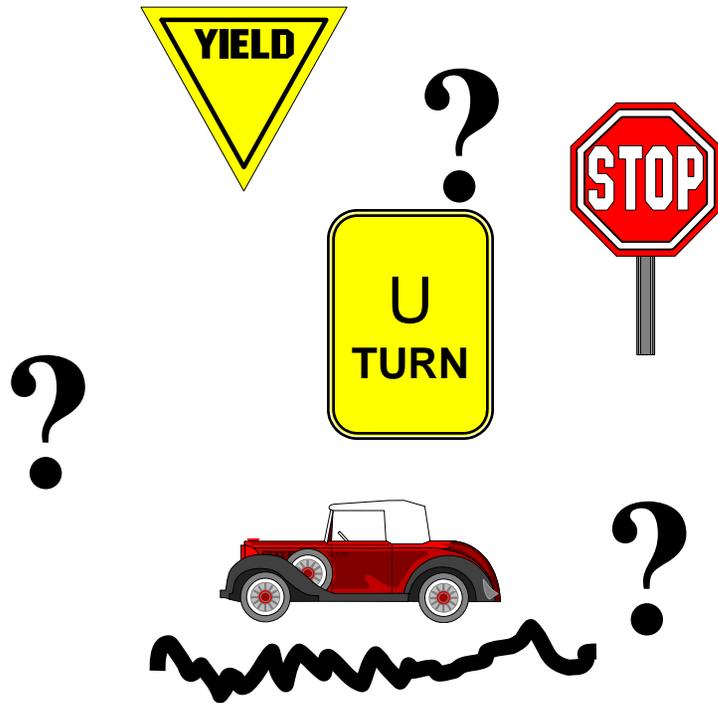
CLIAC Meeting

September 17, 2003



The Goal

From This.....



To This.....





Proposal Overview

- Define Simple and Accurate - Flexible approach
- Define clear roles:
 - Manufacturer's responsibilities
 - Lab Director's responsibilities
- Define Labeling needs





Overlying assumption

- The test has received, or is simultaneously being considered for clearance for professional use.
- What does this mean?



???



FDA Review Components

Professional POC Product	OTC / Home Use Product
Analytical sensitivity / specificity	Same
Method comparison to a predicate device	Same
Linear and /or reportable range	Same
Precision / reproducibility	Same
Normal range	Same
Limit of detection or performance around a cut-off value	Same
Limitations (e.g. environmental, interferences, cross-reactivities)	Same
Labeling is appropriate for user and contains all pertinent information	Same
POC user performance compared to lab method	Lay user performance compared to lab method



CLIA Waiver Step-Wise Approach

Step 1: Determine if the test is simple



Step 2: Determine if the test has an insignificant risk of erroneous result by the end user

Step 3: Determine if the test is accurate

Step 4: Determine if the labeling is appropriate.



Characteristics of “Simple”

- Fully automated, unitized, or self-contained
- Only basic specimen manipulation
- Only basic reagent manipulation
- No operator intervention
- No technical troubleshooting
- No electronic or mechanical maintenance
- No calculations needed to get results



Examples of “Simple”

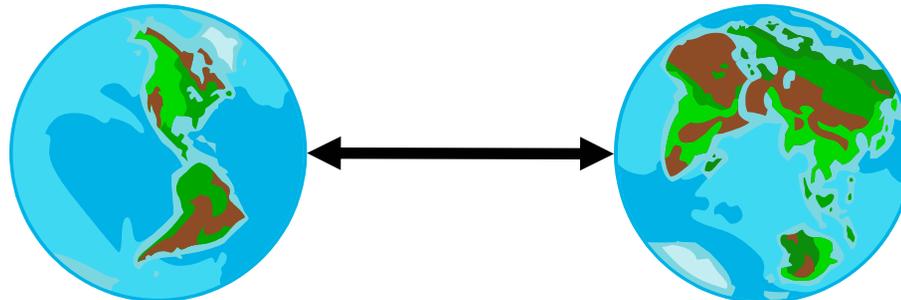
- Specimens: capillary, whole blood, plasma, serum, urine, swabs
- Simple reagent mixing steps
- Results are pos/neg, or numerical
- Results are obvious line or color
- Instructions are 7th grade level or lower





Insignificant Risk of Erroneous Result By the User

- Risk Assessment Approach:
Professional User —————> Lay User
- Mitigate identified risks, provide evidence
- Consistent with FDA's QSR and Europe's IVDD





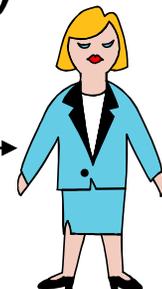
Accurate

- Two-step traceability concept

Step 1. Lay-user results are comparable and traceable to a higher-order lab method, **and**



Step 2. Lay-user results are substantially equivalent to professional results





Accurate

Lay-user =



Lab Professional =



Higher Order

Lab Method



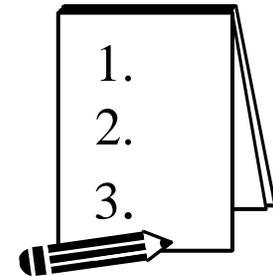
Study Principles

- Demographically diverse users



- Statistically determined number of users
- Simple data analysis methods
- Justified acceptance criteria
- Clear and understandable labeling

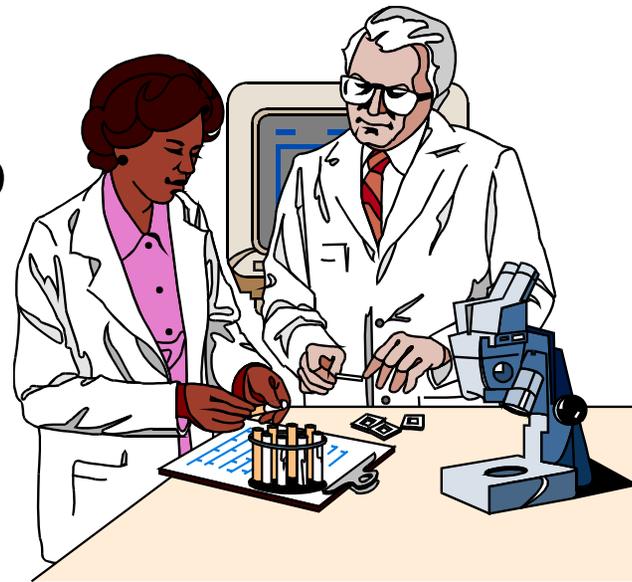
$$1+2=3$$





QC vs. End-User Competency

- QC consistent with risk mitigation measures
- Lab directors must ensure competency
- May utilize QC to do so

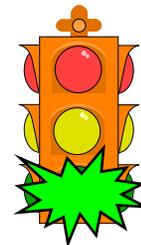


Professional POC Product	OTC / Home Use Product	CLIA Waived Product
Analytical sensitivity / specificity	Same	Same
Method comparison to a predicate device	Same	Same
Linear and /or reportable range	Same	Same
Precision / reproducibility	Same	Same
Normal range	Same	Same
Limit of detection or performance around a cut-off value	Same	Same
Limitations (e.g. environmental, interferences, cross-reactivities)	Same	Same
Labeling is appropriate for user and contains all pertinent information	Same	Same
POC user = Lab method	Lay user = Lab method	Lay user = Lab professional = Higher order lab method
		Test meets definition of simple
		Test has appropriate risk mitigation
		Test has appropriate labeling



Conclusions

- Clear criteria based on science and evidence
- Responsibilities defined and differentiated





Where do we go from here?

- “Negotiated Guidance”
- CLIAC subcommittee
- Get all the parties at the table
- Don’t come out until criteria agreed

