## Developing an External Quality Assessment (EQA) Program

# Robert Martin, MPH, Dr.PH Director, Division of Laboratory Systems, PHPPO, CDC



## External Quality Assessment (EQA) What is it, and is there value?

Thomas L. Hearn, PhD

Deputy Director

Division of Laboratory Systems

Public Health Practice Program Office



### **Quality Assurance**

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**Quality Control** 

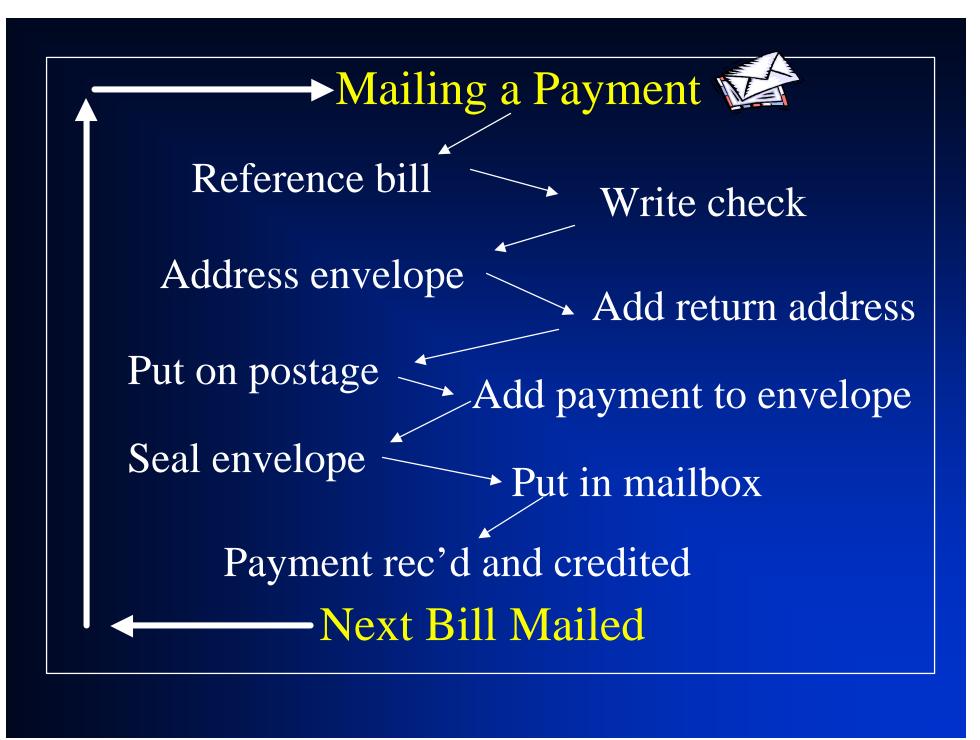
External Quality Assessment or Proficiency Testing



#### **Quality Assurance**

"Planned and systematic activities to provide adequate confidence that requirements for quality will be met" (ISO 8042, 3.4; NCCLS)





#### **Quality Assurance**

#### Staffing

- Qualifications
- Training
- Competency evaluation
- Periodic performance evaluation

#### Infrastructure

- Space
- Supplies

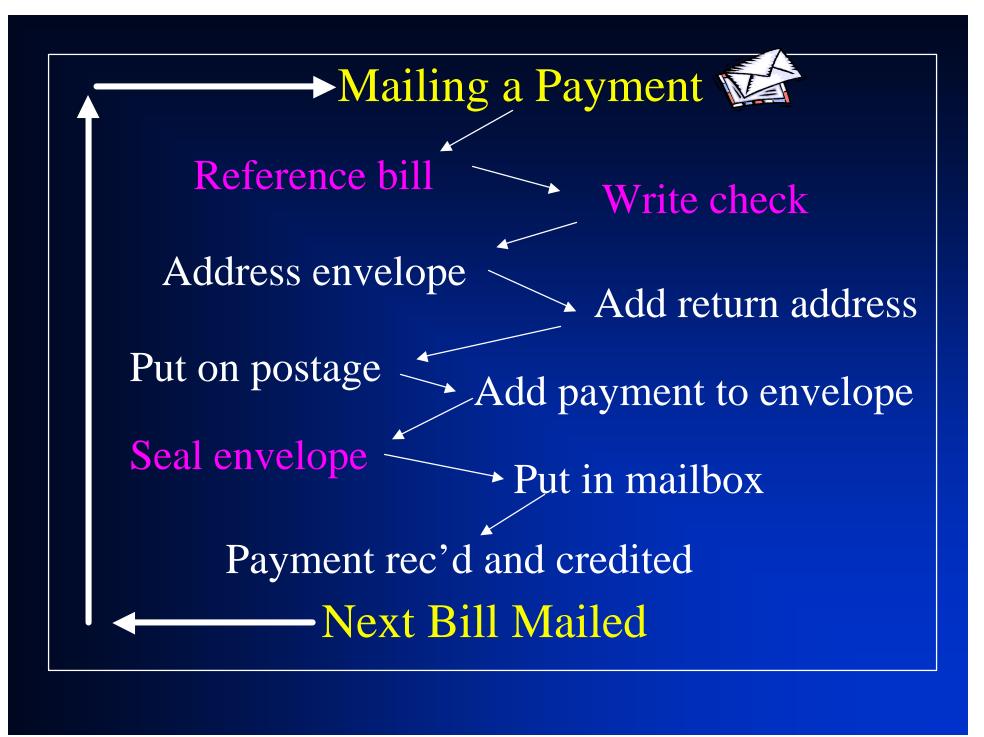


#### **Quality Control**

"Operational techniques and activities that are used to fulfill requirements for quality"

(ISO 8042, 3.4; NCCLS)





#### The Wall Street Journal

Monday: February 2, 1987

"Medical Labs, Trusted as **Largely Being Error - Free** Are Far From Infallible"

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VOL. CCIX NO. 22

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#### **Testing Process**



Pre-Analytic
Test selection
Patient instructions
Test requisition
Collect, label,
and transport specimen

<u>Analytic</u>

Specimen processing
Specimen storage

Reagent preparation Equipment checks Test performance

Post-Analytic
Results review
Quality control review
Report test results
Results interpretation

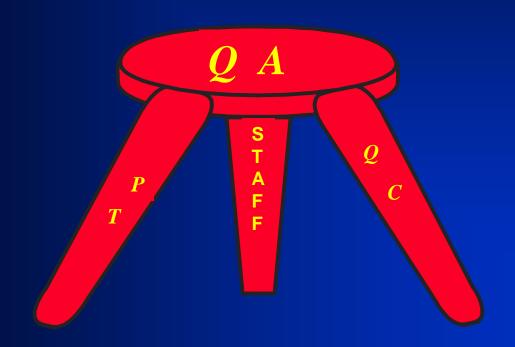


### Laboratory Quality Assurance

- Staffing / personnel
- Quality control (QC)
- Proficiency testing (PT) aka
   External quality assurance (EQA)
- Infrastructure



## Quality Assurance Model U.S. Laboratory Regulations





## **Benefits of Laboratory Quality Assurance**

- Laboratory mistakes are prevented
- Significant improvements in testing performance can be achieved\*

\*Research findings from the College of American Pathologists, the University of Wisconsin, and the Centers for Disease Control and Prevention



## **External Quality Assessment or Proficiency Testing**

"A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others." (NCCLS)



### **Proficiency Testing or External Quality Assessment**

- Central organization sends out challenge specimens for testing, laboratories' results evaluated, laboratories sent scores
- Split specimens exchanged with referral laboratories
- Alternative methods



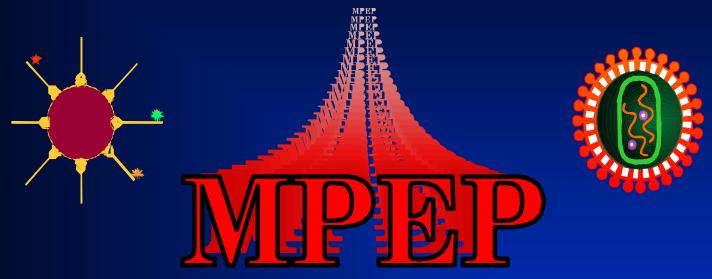
#### **External Quality Assessment**

- Early warning-system for problems
- Measure of laboratory quality
- Valuable benchmarking tool (standardization and traceability)
- Indicator of where to direct improvement efforts
- Monitor of changes in technology and testing practices (evaluation component)



If even the most conservative estimates of gains in improved testing quality are used, thousands of testing mistakes may be prevented yearly by laboratory quality assurance programs.





Model Performance Evaluation Program

### Value of EQA in HIV Testing

#### **Example A**

 Does running external quality control samples with each EIA "batch" improve quality?



#### Study Design

- Study population: HIV labs in MPEP
  - voluntary participation
  - approximately 600 U.S. labs per survey
  - panel of 6 "patient" samples per lab per survey
  - 5 surveys (Aug 94 Aug 96)
  - n=18,600
- Dependent variable: accuracy testing MPEP samples for HIV Ab by EIA



Source: Model Performance Evaluation Program, CDC

### Using External Quality Control Reduced the HIV Error Rate on Performance Evaluation Samples

Sample HIV		Errors With QC Without QC p-value		
Ab Reactivity		WILLII CLC		<u>p-value</u>
Negative	6168	3	19	0.014
Strong Positive	4896	4	3	0.830
Weak Positive	7021	152	307	0.0067
Total	18085 (97.37%)	159 (2.20%)	329 ( 2.90%)	0.0023



SAFER · HEALTHIER · PEOPLE

### Value of EQA in HIV Testing

#### **Example B**

– Do technologists interpret Western blot bands accurately, and can they identify individual bands reliably?



#### Western blot testing practices

- scope of testing
- how testing performed
- interpretative criteria being used

#### Testing performance on HIV....

- highly reactive samples
- weakly reactive samples and,
- non-reactive samples



#### **Study Design**

- Convenience sample: participants in MPEP HIV testing program
- Testing practices: from shipment results and a survey sent March 1999
- Performance data: results for performance evaluation samples mailed in August 1998 and January 1999



## Overall HIV Testing Performance August 1998, All Participants

Samples' HIV Infection Status	Test Used	Number of Results	Interpretations Number (percent)
Positive	EIA	3545	3537 (99.8%) - reactive 8 ( 0.2%) - non-reactive
Positive	WB	1302	1171 (89.9%) - reactive 0 ( 0.0%) - non-reactive 131(10.1%) – indeterminate

Number of EIA laboratories = 701 Number of WB laboratories = 261

Number of reactive samples = 16 (5 weakly reactive)



## Overall HIV Testing Performance August 1998, All Participants

Samples' HIV Infection Status	Test Used	Number of Results	Interpretations Number (percent)
Negative	EIA	708	704 (99.6%) - non-reactive 4 ( 0.6%) - reactive
Negative	WB	131	129 (98.4%) - non-reactive 0 ( 0.0%) - reactive 2 ( 1.6%) – indeterminate

Number of EIA laboratories = 701 Number of WB laboratories = 261

Number of non-reactive samples = 2



### Overall HIV Testing Performance January 1999, All Participants

Samples' HIV Infection Status	Test Used	Number of Results	Interpretations Number (percent)
Positive	EIA	2919	2914 (99.8%) - reactive 5 ( 0.2%) - non-reactive
Positive	WB	1070	986 (92.1%) - reactive 2 ( 0.2%) - non-reactive 82 ( 7.7%) – indeterminate

Number of EIA laboratories = 724 Number of WB laboratories = 267

Number of reactive samples = 16 (5 weakly reactive)



### Overall HIV Testing Performance January 1999, All Participants

Samples' HIV Infection Status	Test Used	Number of Results	Interpretations Number (percent)
Negative	EIA	1452	1448 (99.6%) - non-reactive 4 ( 0.6%) - reactive
Negative	WB	258	253 (98.1%) - non-reactive 1 ( 0.3%) - reactive 4 ( 1.6%) – indeterminate

Number of EIA laboratories = 724 Number of WB laboratories = 267

Number of non-reactive samples = 2



#### Sources of Discordant Western Blot Interpretations

- Incorrect bands with correct interpretation ~62%
- Correct bands with incorrect interpretation ~36%
- Incorrect bands with incorrect interpretation ~2%

Source: Serologic Testing for HIV-1: Status of Western Blot (WB) Testing and Inconsistent Interpretation of WB Testing Results in a Model Performance Evaluation Program (MPEP) - 1989-1992. S.O.Blumer, W.O.Schalla, J.H. Handsfield, J.S.Hancock, G.D. Cross, and T.L. Hearn. [Presented June 7-11, 1993 at the IX International Conference on AIDS in Berlin, Germany]



### Number of Different Blot Patterns, August 1998 and January 1999

Samples' HIV Infection Status	Number of Samples	Number of Different Blot Patterns for Each Sample
Negative	2	3, 5
Positive	11	7, 8, 9, 13 (2), 14, 16 (3), 28, 29
Positive (Weakly reactive)	5	29 (2), 38, 42, 48

<sup>-</sup>Bands reportable: p17/18, p24, p31/32, gp41, p 51, p55, p66, gp120, and gp160

n= 187 in 1998 and n= 197 in 1999

<sup>-</sup>U.S. laboratories only

#### Value of EQA

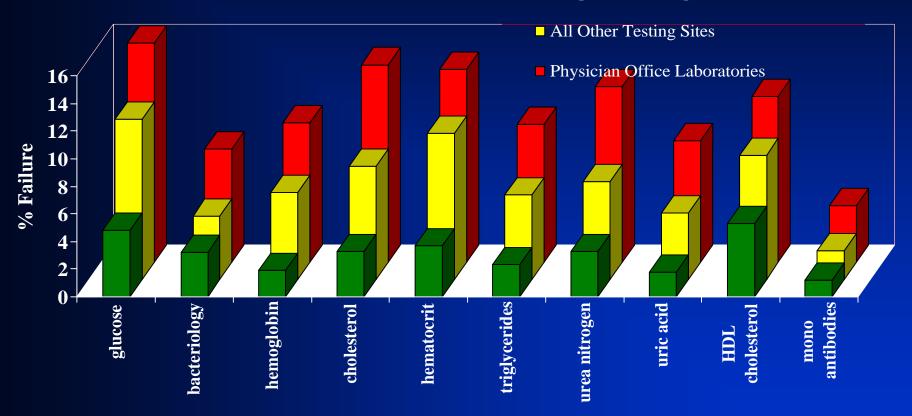
#### **Example C**

– Do laboratories that have participated in mandated laboratory EQA programs perform better than laboratories that have not participated?



### **Proficiency Testing Failure Rates**

■ Hospitals and Independent Laboratories



1994 HHS approved proficiency testing providers



## External Quality Assessment (EQA) What is it, and is there value?





#### THANK YOU!

