

Developing an External Quality Assessment (EQA) Program

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External Quality Assessment (EQA)

What is it, and is there value?

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Quality Assurance

?????

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)

Mailing a Payment



Reference bill

Write check

Address envelope

Add return address

Put on postage

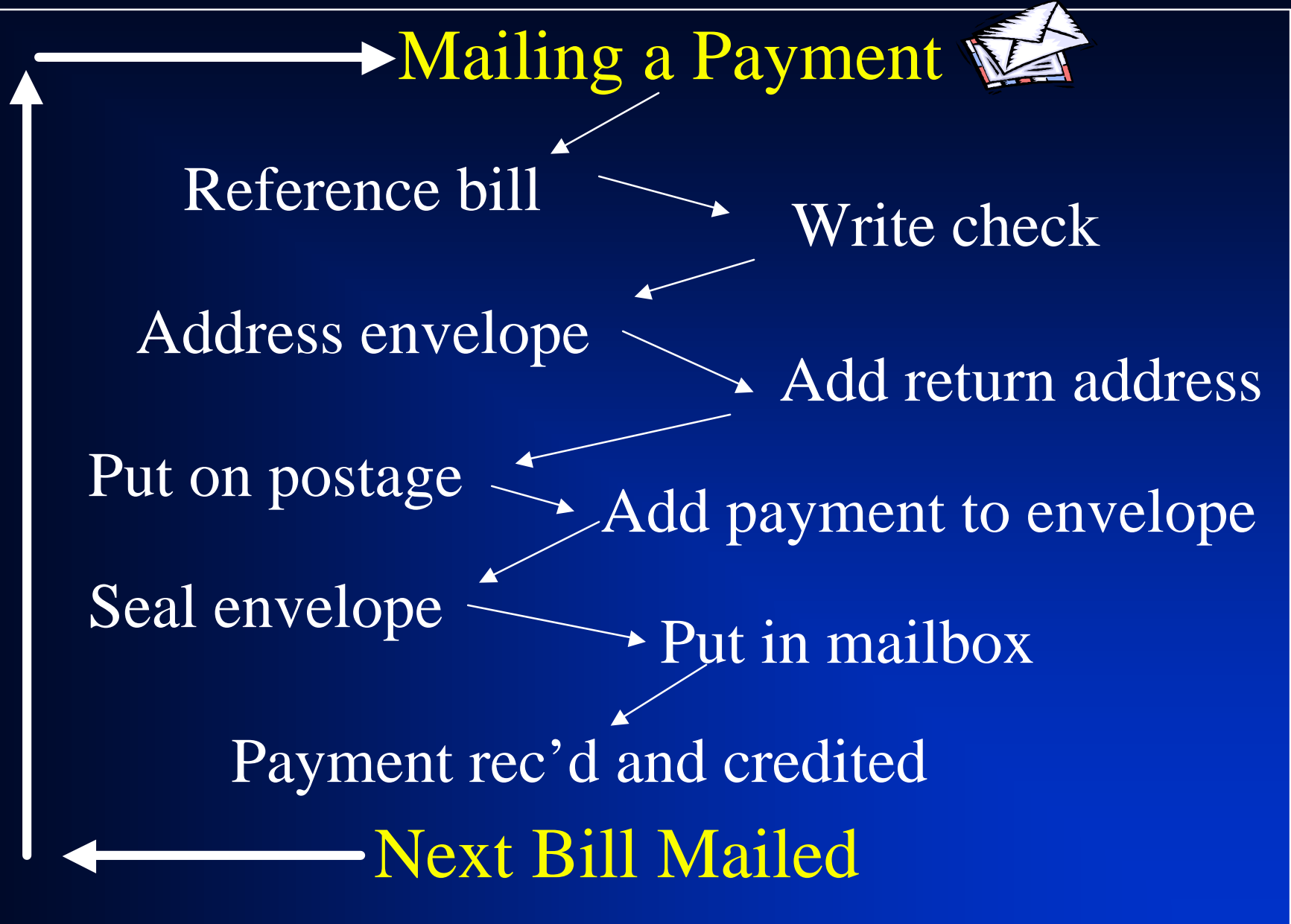
Add payment to envelope

Seal envelope

Put in mailbox

Payment rec'd and credited

Next Bill Mailed



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)

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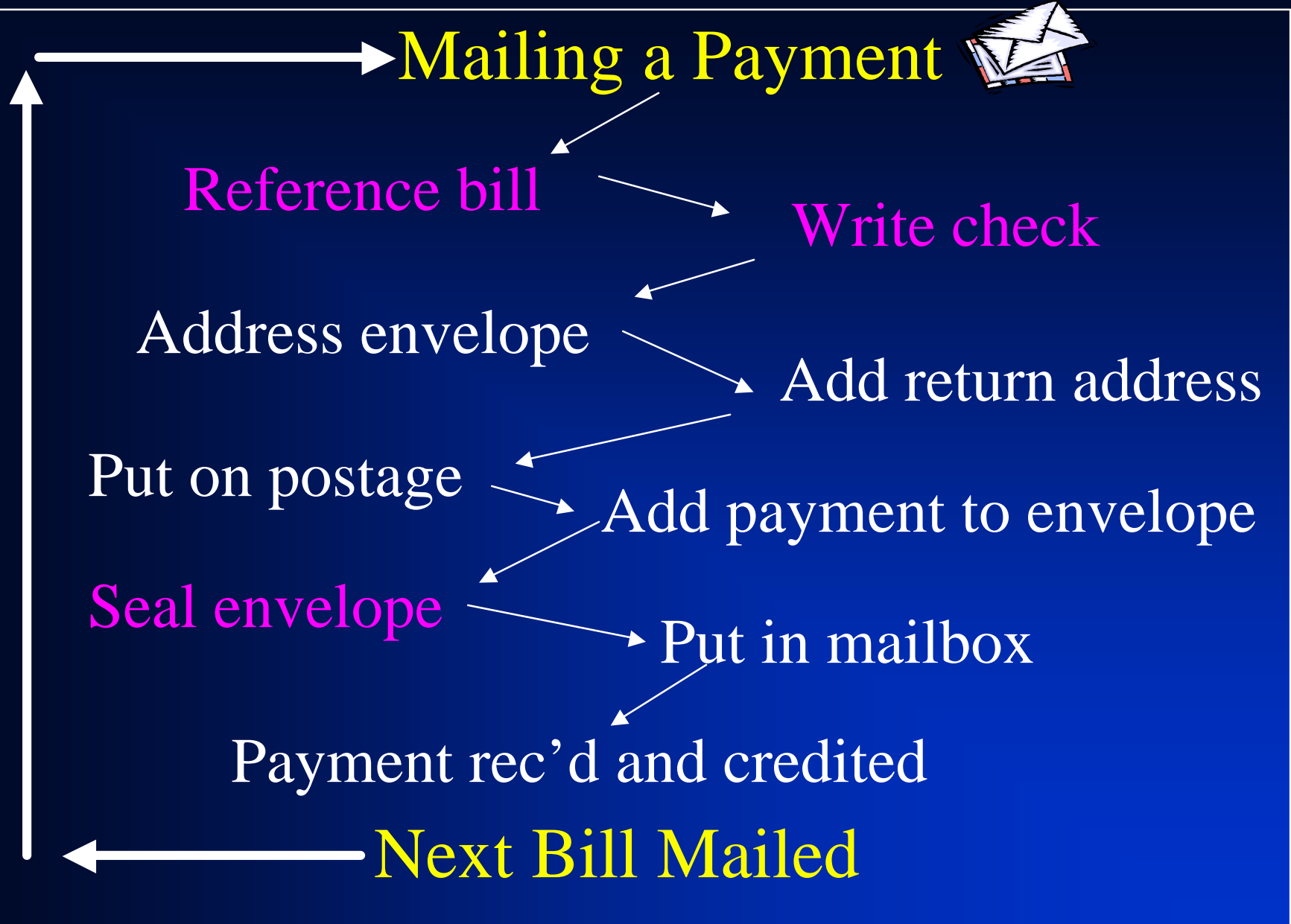
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The Wall Street Journal

Monday: February 2, 1987

“Medical Labs, Trusted as Largely Being Error-Free Are Far From Infallible”

THE WALL STREET JOURNAL

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Carrying Over

MONDAY, FEBRUARY 2, 1987

Finance, First Edition

30 CENTS

Deep in Hock

Debt Keeps Growing, With the Major Risk In the Private Sector

Many Analysts See Defaults Soaring in Any Recession. Balance Sheets Weaken

Households Are Under Strain

By Charles H. Schwab Jr.
 The Federal Reserve Bank of New York's latest report on the U.S. economy, due out next week, is expected to show that the private sector's debt is growing rapidly, and that households are under strain. The report is expected to show that the private sector's debt is growing rapidly, and that households are under strain. The report is expected to show that the private sector's debt is growing rapidly, and that households are under strain.

Even though most economists still think a recession is unlikely, some are warning that the private sector's debt is growing rapidly, and that households are under strain. The report is expected to show that the private sector's debt is growing rapidly, and that households are under strain.

What's News

Business and Finance World-Wide

TRADE DEFICIT increased sharply in December, despite the weak private sector. Analysts said the \$1.6 billion gap, the smallest since March 1985, suggests the dollar is made weaker by the market but hasn't turned around yet. Meanwhile, the Fed's latest actions decided not to meet this week. It could raise and the dollar.

EMERSON Corp. unveiled an option to buy 5% of the shipping giant. Edgar J. DeBorja, Emerson's chief executive, said the company is still in the process of selling its assets. He said the company is still in the process of selling its assets.

ARMED Air transport company said it will pay \$100 million to buy back its stock. The company is still in the process of selling its assets.

AS Morgan Guaranty banker, Angelo Calabro, was arrested in 25 years in prison and fined \$100,000 for creating evidence of dollars from thin air.

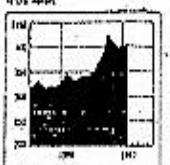
PHILIP authorities detained a suspect in the last stage of the investigation. The suspect, a man, was seen in a public place. The suspect, a man, was seen in a public place.

WHILE there were no reports of a strike, the company is still in the process of selling its assets. The company is still in the process of selling its assets.

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Gold Prices



Gold was priced in New York at \$400 a Troy ounce Jan. 31. It was up from \$350.50 on the last trading day.

Professional Hunter

Of Bears and Cougars Also Hunt Security

Threats to National Security in an Endangered Species

By Ken Belson

THE Department of Justice is looking for a wide range of threats to national security. The department is looking for a wide range of threats to national security.

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The Outlook

There's No Easy Fix For Dollar Volatility

WASHINGTON
 The past two weeks' turbulence in the currency markets has only added weight to the shortcomings of fiscal and exchange rate.

IT is not just the short-term volatility that is troubling. Over the past few years, the dollar has declined from record highs against the West German mark and the Japanese yen to record lows. Just before that, from 1980 through early 1983, it rose to 12 1/2 percent above.

THE outlook is still uncertain. The outlook is still uncertain. The outlook is still uncertain.

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False Negative

Medical Labs, Trusted As Largely Error-Free, Are Far From Infallible

LAST minute equipment specimen mix-ups afflict even best labs at times. Regulation weak and costly.

THE medical industry is still in the process of selling its assets. The medical industry is still in the process of selling its assets.

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Testing Process

Pre-Analytic

Test selection
Patient instructions
Test requisition
Collect, label,
and transport specimen

Analytic

Specimen processing
Specimen storage
Reagent preparation
Equipment checks
Test performance

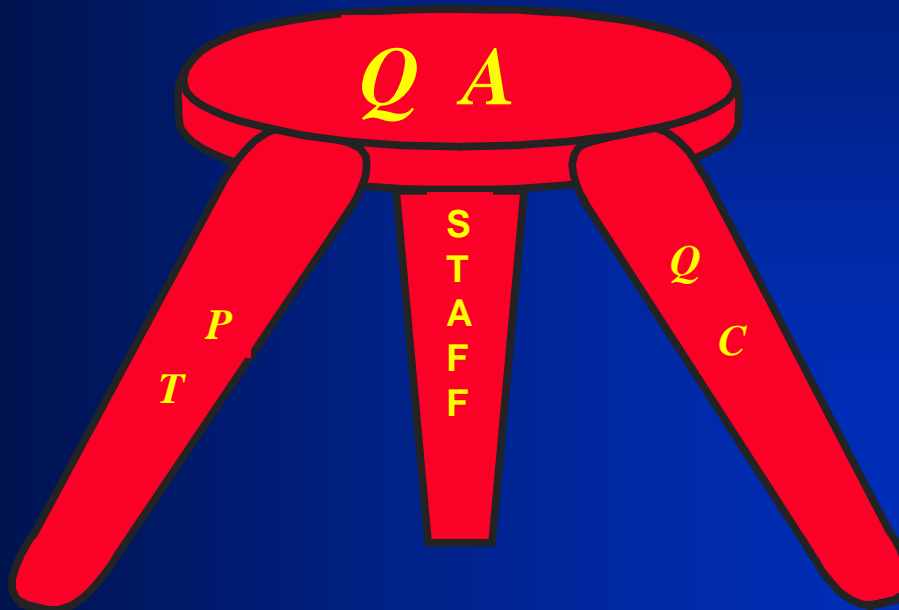
Post-Analytic

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)

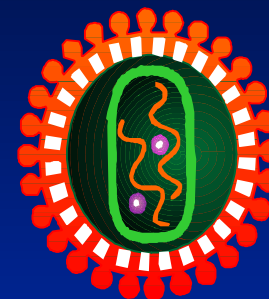
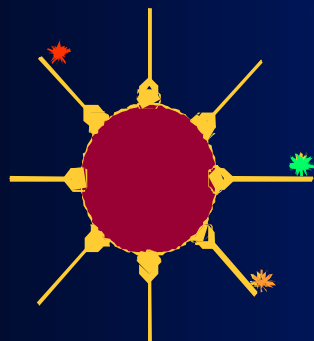
Proficiency Testing or External Quality Assessment

- **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.



MPEP

Model Performance Evaluation Program

CDC

March 2000

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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

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



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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)

Source: August 1998 Performance Evaluation Shipment



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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)

Source: January 1999 Performance Evaluation Shipment



March 2000

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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

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

-U.S. laboratories only

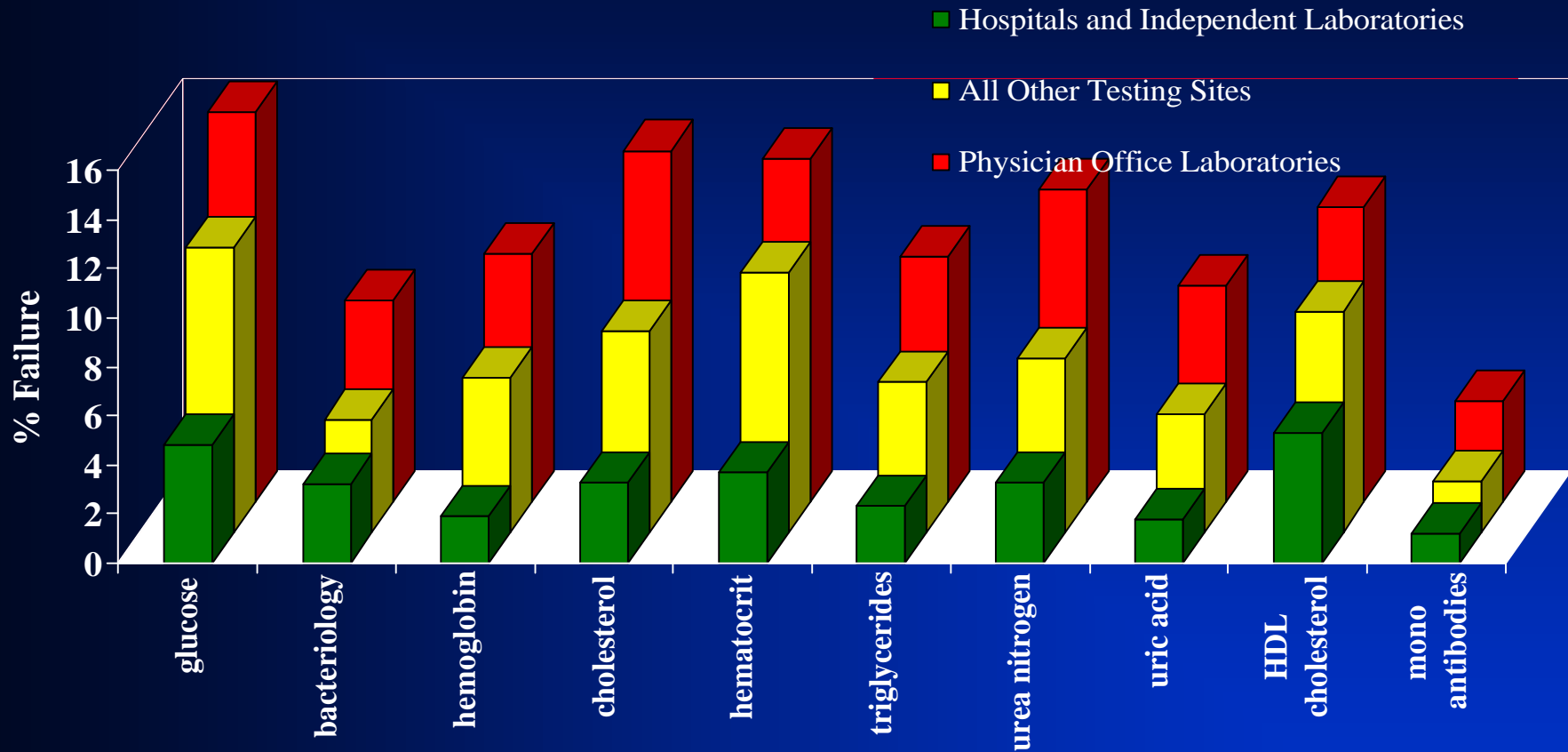
n= 187 in 1998 and n= 197 in 1999

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



1994 HHS approved proficiency testing providers



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External Quality Assessment (EQA)

What is it, and is there value?



THANK YOU!

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