

Proficiency Testing

Why is it important?

How can you make it work for you?

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In 30 minutes or less:

- The importance of PT – justifying its use
- A little history of the subject
- What PT can do for you
- What PT ***could do*** for medicine, world health
- Where to begin?

Why is PT important?

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IHT Sept. 17, 2007

Cancer-free, and weighing mastectomy

DNA tests provide early guide to risk

By Amy Harmon

CHICAGO: Her latest mammogram was clean. But Deborah Lindner, 33, was tired of constantly looking for the lump.

Ever since a DNA test had revealed her unusually high chance of developing breast cancer, Lindner had agonized over whether to have a mastectomy, a procedure that would reduce her risk by 90 percent.

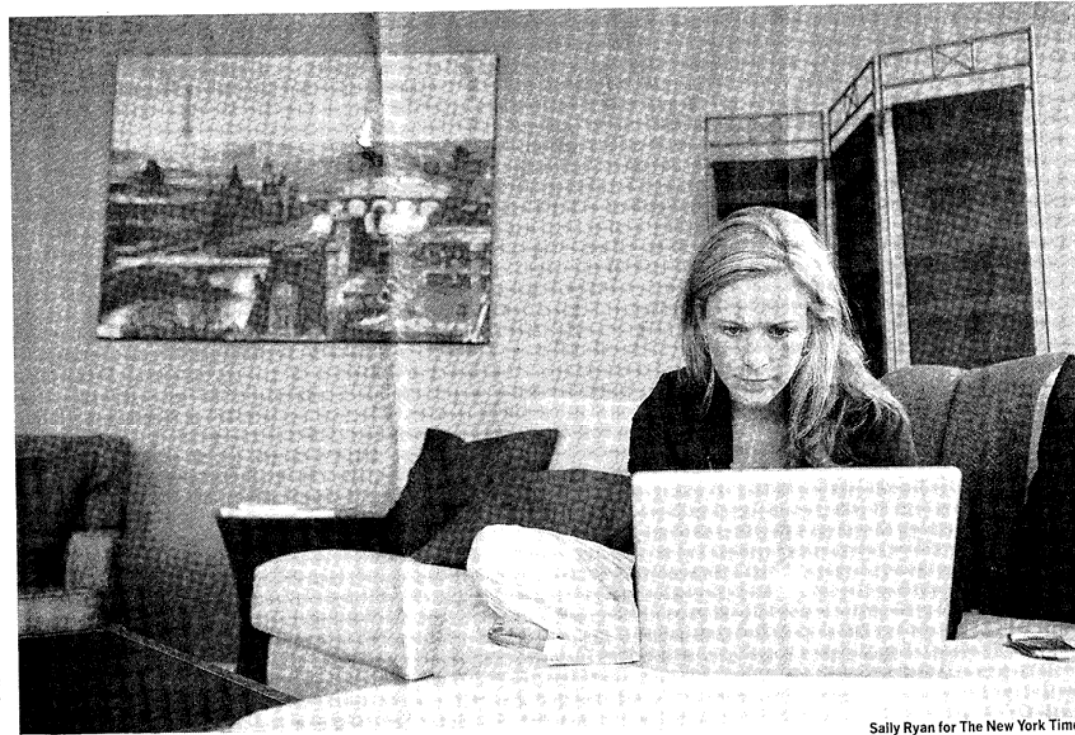
She had stared at herself in the mirror, imagining the loss of her familiar shape. She had wondered, unable to ask, how the man she had just started dating would feel about breasts that were surgically reconstructed, incapable of feeling his touch or nursing their children.

But she was sure that her own mother, who had had chemotherapy and a mastectomy after a bout with the cancer that had ravaged generations of her family, would agree it was necessary.

"It could be growing inside of me right now," she told her mother on the phone in February, pacing in her living room here. "We could find it anytime."

Waiting for an endorsement, she added, "I could schedule the surgery before the summer."

But no approval came



Sally Ryan for The New York Times

More reasons why PT is important

- Objective evidence of your lab's competence
- Component of a quality improvement program
- Shared experience
- Globalization
- Supplements IQC
 - Sensitivity
 - Specificity

Play by the PT rules for your own sake...

- If only your best tech runs PT...
- If you always run PT right after calibration or maintenance...
- If you run your PT samples multiple times and report the average...

It is in your own interests to understand how well your lab works!

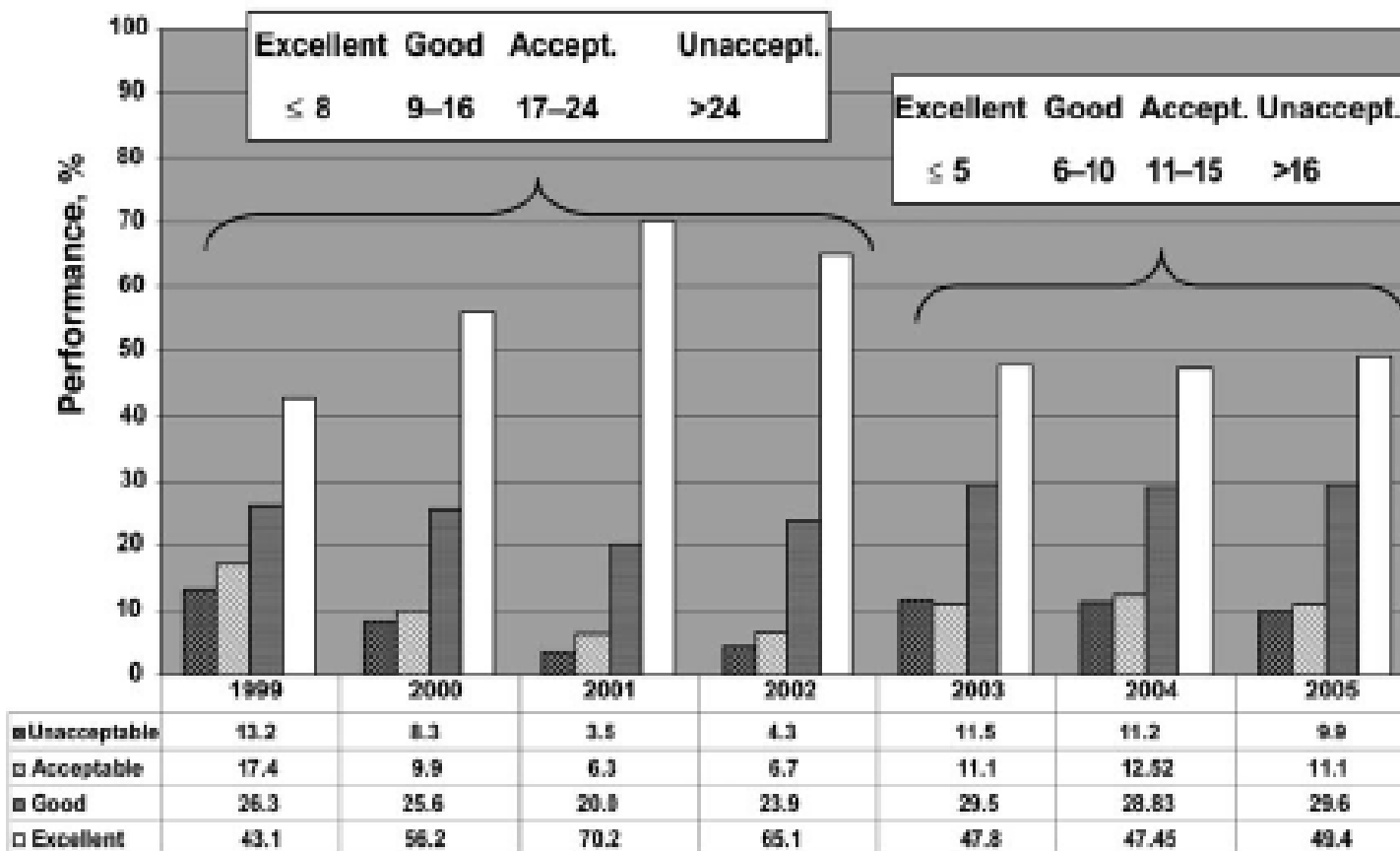
Do your Technologists 'optimize' tests?

- Most scientists have a little 'engineer' in them
- If you make your tests (lab-developed or home-brew tests), optimizing is important during development
- For test methods, the 'make or buy' issue has mostly moved to 'buy'
- Commercial test kits should be used 'as is'
- PT is crucial for both kinds of tests



Quality Improvement

CK-MB mass



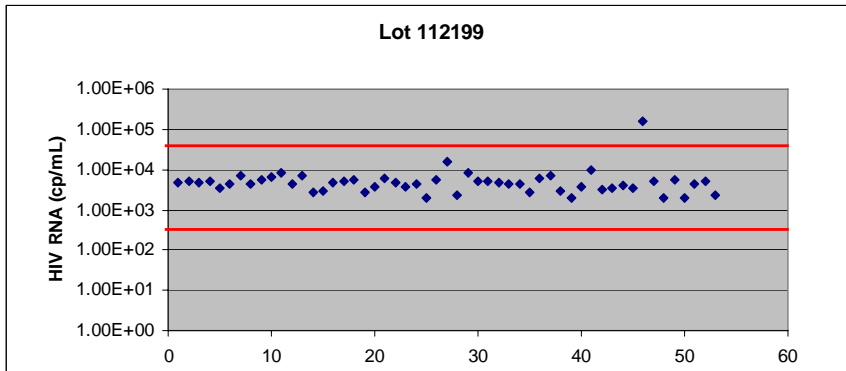
Shared experience:



People move:



PT supplements your IQC:



PT and Internal Quality Control

IQC keeps you on track between PT events.

Qualitative tests have only one medical decision point, at the cutoff!

Your IQC should include a low positive to monitor variability near that all-important cutoff.

Those QC results should alert you to shifts in sensitivity.

IQC isn't much help with specificity.

PT samples provide variety and possibly more positives or more negatives than you normally see.

A History of PT (in the U.S.)

1895: first U.S. clinical lab

1946: Committee of Laboratories of the Medical Society of Pennsylvania – 1st survey

(Belk WP, Sunderman FW. Am.J.Clin.Pathol. 1947;17:553-61)

CAP did two national surveys soon thereafter

Results were so bad the CAP Board of Governors requested that they not be published.



F. William Sunderman, Sr.

1898-2003

After this disaster...

Sunderman and colleagues began a monthly survey for chemistry analytes.

That survey continued for 36 years, until 1985.

Each report included a bibliography and literature review.

At its peak, more than 2000 labs participated.

How do labs improve?

Michael Noble looked at whether 'external evaluation' of laboratories improves patient safety.

By external evaluation, he meant PT/EQAS and accreditation.

PT/EQAS? No problem!

Repeatedly, experience has demonstrated that laboratories improve when they participate over time in PT.

Does accreditation improve labs?

Few studies – results less clear.

Noble also compared the quality of PT results from accredited labs and those not accredited in Canada – no difference!

His tentative conclusion: accreditation may improve lab performance and patient safety, but it's difficult to prove this.

My reading of his results: PT is a significantly stronger tool for promoting laboratory improvement.

BEST CASE: PT with education and followup

How to make PT work for you?

If you're like my brother, you plunge right in...



Good guidance is available

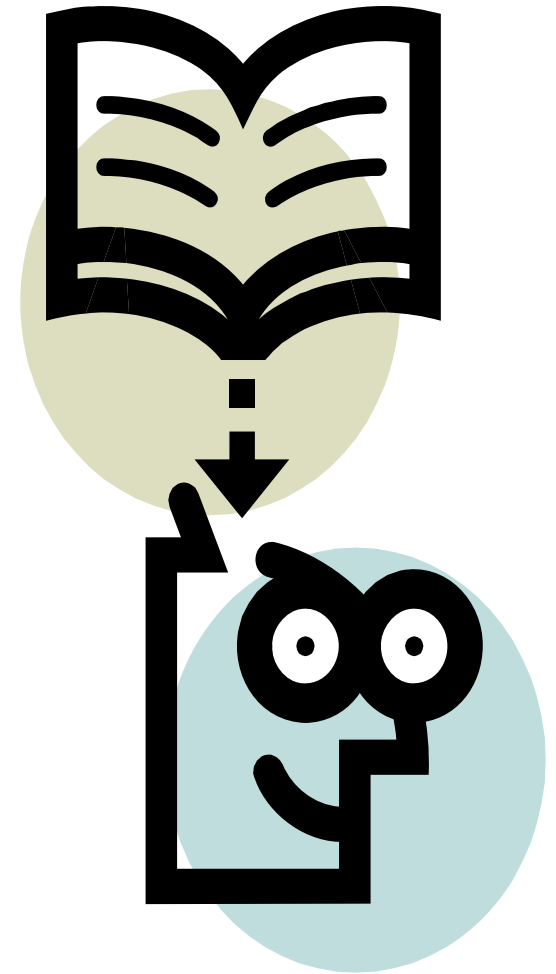
GP27-A2

Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition (2007)

www.clsi.org



*(Formerly NCCLS)
Providing NCCLS standards and guidelines,
ISO/TC 212 standards, and ISO/TC 76 standards*



Especially when things are going well

- Review your results over time
- Watch for trends in your own lab
- Look for useful information in the survey summaries:
 - Other users of your method?
 - Other methods?
 - Are the samples challenging?
 - Repeat samples allow reproducibility checks

Help from GP27 to set up your program

It's going to happen – one day you'll have a bad result:

- ✓ Be ready – plan in advance
- ✓ Train your staff on the investigation process
- ✓ That will also help prevent bad results!

Transfusion Medicine Investigation of Discordant Proficiency Testing Finding

Effective

Date: _____

Document # / Version #

Transfusion Medicine Investigation of Discordant Proficiency Testing Finding

Survey Name and Number _____ Date Testing Performed _____

Please answer the following questions:

1. Was testing material received in satisfactory condition? Yes No

If no, explain. _____

2. Was the problem related to any of the following? Explain any checked boxes on page 2.

Investigations can be organized, consistent

Below is a section of the GP27 investigation checklist from the form:

Technical operation of method

- 12. Incorrect testing method chosen
- 13. Written procedures not followed
- 14. Instructions on analysis worksheet not followed
- 15. Manufacturer's instructions not followed
- 16. Inappropriate reagents used for testing
- 17. Failure to add reagent/sample to test system
- 18. Failure to act on inappropriate QC results
- 19. Samples mixed up on bench
- 20. PT material improperly prepared or stored

Error Categories

There are only two (or maybe three) kinds of error, but there can be many sources.

Classifying these can help you find problem areas and formulate solutions;

- Clerical
- Methodological
- Equipment
- Technical
- PT sample
- Result evaluation
- No explanation

Vendor-lab cooperation



GP27 also provides a report format that inspectors will love!

Appendix C. Sample Form for Documenting Unacceptable PT Investigations

XYZ Laboratory Unacceptable PT Investigation

Date of Investigation:

PT Set Identification:
Date:
Unacceptable result:
Acceptable result/range:
Previous trends/unacceptable results for this analyte/test:

And when you get it all right, this is how you'll feel!



Thank you! And I hope I can answer your questions...



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