


Annual Proficiency Testing (PT) Training 2016

Read and review the PowerPoint presentation that follows.

It was intended to be presented as a slide show with audio. Use your mouse to hover over the symbol at the top left corner to see the explanation for any particular slide. 

The PT Guidelines brochure is attached at the end of the presentation. Print a copy for yourself.

After reviewing the material, take the quiz that follows. You **must score 100 to pass** the quiz. If your score is less than 100, see your supervisor and follow the normal process to request a reset.

Note: you can refer to the presentation and/or the brochure when taking the quiz.

A copy of the PowerPoint presentation is also printed and available at each lab site if you prefer to review a hard copy.



Proficiency Testing: Back to the Basics

Guidelines for Communication and Handling of
Proficiency Material

2016 QHL PT Training Part One





Agenda

- The Five Why's of PT
- Proficiency Testing (PT) Basics
- PT Never Leaves the Four Walls
- Questions from the Labs
- Proficiency Testing Questions / Resources
- Consequences for Intentional Referral
- Next Steps

WHY?

WHY? WHY? WHY?

WHY?



The 5 WHY's of Proficiency Testing

Why do we do Proficiency Testing?

- It is a regulatory requirement (CAP, CLIA, some states).

Why is PT important?

- PT shows the laboratory's ability to provide accurate / reliable results and alerts us to areas of testing that are not performing as expected.

Why do we use PT providers?

- The use of PT providers allows for a comparison of our laboratories' performance to other laboratories in the industry.

Why are all phases included?

- PT includes the pre-analytical, analytical, and post-analytical phases to help ensure accuracy of patient specimen handling, testing and reporting.

Why do we review PT internally?

- Internal reviews may indicate subtle shifts and trends that over time may affect patient results.



Who Sets the Requirements?

The Federal Government as cited in CLIA 493.801

493.801 Enrollment And Testing Of Samples

- The laboratory must participate in a CMS-approved proficiency program for all CLIA specialties and sub-specialties included in the laboratory's testing menu.
- If a proficiency test program is not available, the analyte must be challenged by an Alternative Performance Assessment at least twice per year.
- Where required, the laboratory must also enroll in state mandated PT programs.



Annual PT Training: AGAIN???

YES! – that is why it is annual!

What is still happening?

- Confusion still exists for some employees.
- PT samples are being accidentally referred to other labs
- Inappropriate discussions about PT are still occurring
- Slides / instrument print outs / submission forms have been sent outside of the performing laboratory for review
- We have received PT samples from clients



Remember The Basics

What are the requirements?

- DO NOT Accept or Test PT material FROM another laboratory
- DO to the extent possible, test PT samples the same as patient samples UNLESS the patient sample would be referred
- DO NOT Communicate PT results or information on active PT surveys within or outside of your lab prior to the formal evaluation by your PT provider (Quest Mandate)
- DO NOT Refer any portion of a PT sample TO another laboratory

**DO NOT Accept or
Test PT material
FROM another
laboratory**



How could this ever happen? (1/2)

Unintentionally:

- A nearby hospital lab sends a rack of specimens to you because their chemistry analyzer is down and fails to remove the PT samples included in the batch
- A nearby lab sends you their PT samples to run as part of their troubleshooting process



How could this ever happen? (2/2)

Intentionally:

- A nearby hospital lab sends their PT samples to your lab because your tech asked for them. She was assigned to run the same survey but spilled her samples and called her friend down the street for help.
- A nearby stat lab sends their PT samples to your lab (ordered like a patient of a client) to double check their own results.

How can we tell if it is PT material?

Use the Quest Suspect PT Poster!



ATTENTION! SUSPECT PROFICIENCY SAMPLES



IF THE FOLLOWING ACRONYMS APPEAR ANYWHERE
ON THE PATIENT RECORD OR IF THE PATIENT IDENTIFICATION
IS CODED AND REFLECTS ANY OF THE ACRONYMS
BELOW WITH A TWO DIGIT NUMBER
(e.g., CAP-04, K-01, NYS-02, Survey-03, Penn-05, ...)

**AAB, AAFP, ACCU, ACCUTEST, ACP,
API, ASCP, ASIM, CAP, CTS, EXC,
EXCEL, MLE, NYS, PROFICIENCY,
PROF, PENN, SURVEY, WSLH**

DO NOT:

- ACCESSION THE ORDER
- TEST THE SAMPLE
- REFER THE SAMPLE
- ENGAGE IN EXTERNAL COMMUNICATION ABOUT THE SAMPLE





Do you know where to find this poster?

If you do not have this poster displayed in the area where specimens are received,

ask your supervisor to obtain one from your local Quest BU.



Suspect PT Poster Reminds us that:

Samples should be considered suspect PT if:

- “AAB”, “AAFP”, “ACCU”, “ACCUTEST”, “ACP”, “API”, “ASCP”, “ASIM”, “CAP”, “CTS”, “EXC”, “EXCEL”, “MLE”, “NYS”, “PROF”, “PROFICIENCY”, “SURVEY”, “PENN”, or “WSLH” is included in the patient identification.
- The sample or requisition has any of these words AND a 2 digit number (e.g., CAP, K-O, SURVEY 08, PROFICIENCY SAMPLE- 09 or PENN-03).
- The words “Proficiency” or “CAP” or “Survey” appear on the label or requisition, or identification is similar to that used for PT.
- The specimen appears to be a commercially prepared product or has the physical characteristics compatible with the consistency of an active PT survey sample.
- You are in the process of participating in a PT survey with a similar name or sample type.

If a requisition and / or sample has any of the above terms or abbreviations AND is NOT from your own lab,



And tell your supervisor immediately!



Questions to Ask:

Q: Is this PT material? (see Suspect PT Poster)

A: No – process as a patient sample

A: Yes – go to the next question

Q: Where did the sample come from?

A: From our own lab- then it is OK to process

A: If NOT from our own lab, (maybe from a client or sister lab) -- then

Do Not Process, alert your supervisor!

Where did sample come from?

From CLIENT

From Sister Lab

From our lab



Only acceptable pathway for PT to enter the testing area is from our own lab

DO to the extent possible,
test PT samples the same
as patient samples
UNLESS the patient
sample would be referred



PT Sample Checklist for Testing Personnel (1/2)

Every time I handle a PT sample I ask:

1. Am I treating this PT sample like a patient sample—as much as I possible can?

Key Points:

- a. Run PT samples in the next batch with patient samples.
 - Add a notation to the survey paperwork if no patient samples were available to run as a batch.
- b. Follow SOP for repeats
 - Be sure to only repeat tests as required by specific SOPs.
 - Watch out for automatic battery repeats!
- c. Consultations – if allowed in the SOP
 - Document consultations with peers or your laboratory director the same way you would for patient samples.



PT Sample Checklist for Testing Personnel (2/2)

2. Does the normal patient sample require send-out to another laboratory for confirmation (like HIV1/2)?
 - If YES, perform initial testing on the PT samples and then immediately separate them from the run. **DO NOT SEND OUT!**

3. When testing is completed, is the PT stored appropriately?
 - PT should be sequestered away from patient samples to help prevent inadvertent referrals or inappropriate use.

4. If I work at more than one lab – did I already do testing for this PT event?
 - If YES, notify your supervisor.



PT Sample Checklist for Supervisors / Managers

Every time I handle a PT sample for routine proficiency testing I ask:

1. Is the material identified as PT?
2. Is the paperwork correct?
3. Is PT being rotated appropriately among all techs, on all shifts?



PT Sample Checklist for Supervisors / Managers

After Every PT survey is complete, I ask and then check:

1. Did we treat the PT material like a patient sample?
 - ✓ Ran with samples – or documented why not
 - ✓ Followed the SOP for repeat instructions
 - ✓ Followed the SOP for consultations and documented appropriately

2. Is there a risk of sending this PT to another laboratory for confirmation?
 - ✓ All PT remained in the lab, even if patient testing would be sent out for a reflex test.

3. Have we stored the PT samples appropriately?
 - ✓ Sequestered away from patient samples to help prevent inadvertent referrals or use prior to formal evaluation is complete.

PT Sample Checklist for Supervisors / Managers

Every time I use a PT sample for anything other than for routine proficiency testing I ask:

1. Is this Active PT?
 - Have we received the formal evaluation from the PT provider?
2. Is the PT being used for competency assessment?

PT may NOT be used for anything other than competency assessment and only after the formal evaluation by the PT provider has been completed.

**DO NOT Communicate
PT results or information
on active PT surveys
within or outside of your
lab prior to the formal
evaluation by your PT
provider (Quest Mandate)**

PT Sample Checklist: COMMUNICATION

Every time PT is mentioned, I think:

1. Is this active PT?
2. What should I do...
 - a. If I receive a call from a nearby hospital laboratory, or
 - b. If a co-worker asks a question about it, or
 - c. If the supervisor of a sister-lab asks about it (e.g. potential reagent lot issue), or
 - d. If a doctor's office indicates, "oh, that's our PT sample," when you call a critical?

Key Points: The actual PT results CANNOT be discussed.

If you have concerns about the PT survey:

Discuss with your supervisor

Order a replacement survey

If you suspect that the MD's office sent the PT sample for your lab to run:

Tell your Supervisor immediately!

!

PT Sample Checklist: PAPERWORK

Every time I come in contact with PT paperwork I think and check:

1. Is this active PT?
2. Is it OK to send the active PT paperwork to my supervisor / lab director when he or she is working at a different location?
 - NO – it must stay within the four walls

DO NOT Refer any portion
of a PT sample TO
another laboratory



How could this ever happen?

Remember how another lab could unintentionally send PT samples to our lab?

We could unintentionally do it too.

- If we send a rack of specimens to a nearby lab because our chemistry analyzer is down, we **MUST NEVER FAIL** to remove the PT samples included in the batch!
- We **MUST NEVER** send our PT samples to another lab for them to run as part of our troubleshooting process!



PT Sample Checklist: for Sendouts

I am always alert to unintentional actions resulting in PT sample referrals:

1. Do I notice CAP or other acronyms when reviewing Send-Out worksheets?
2. Do any specimens packaged for send outs look unusual?

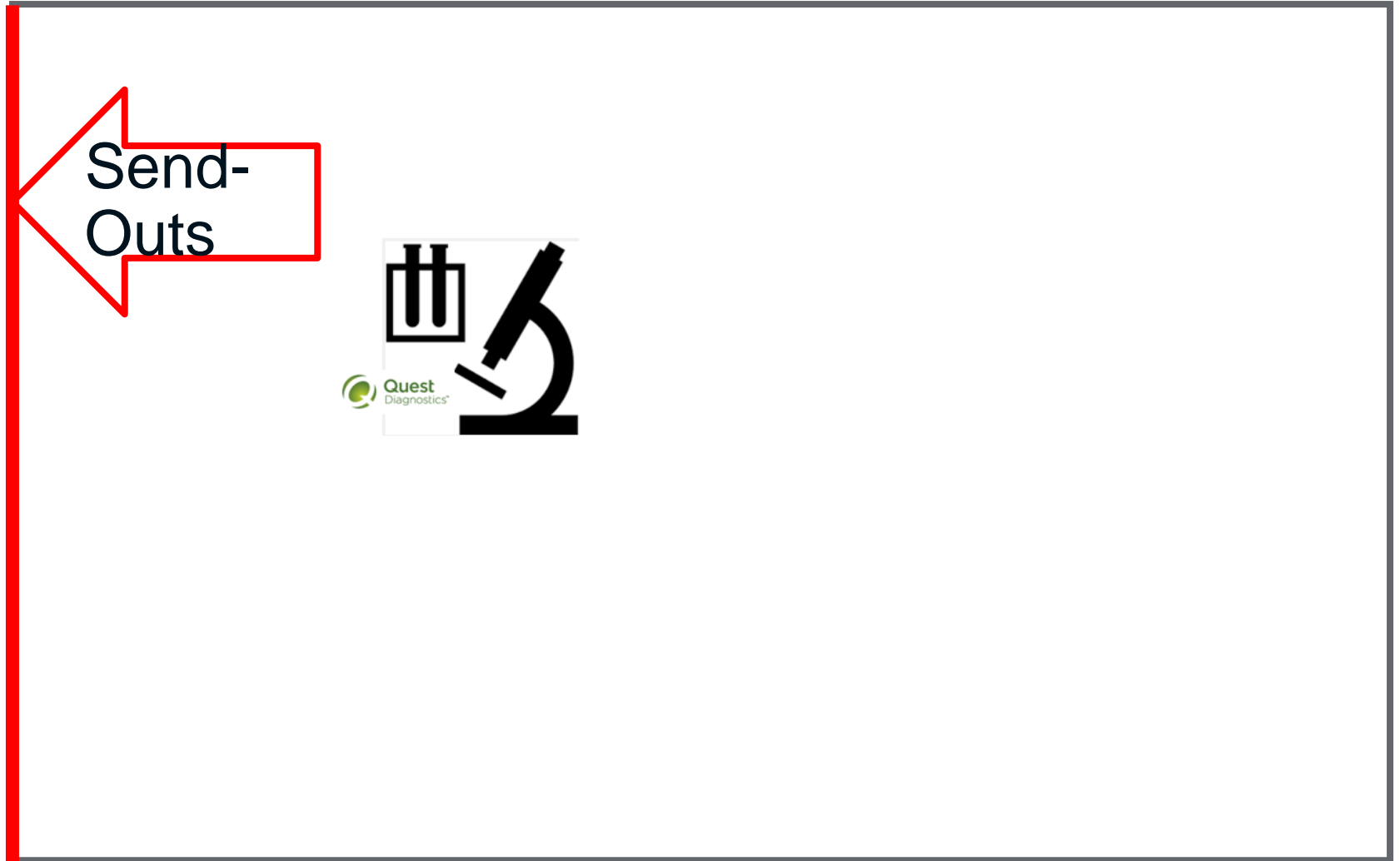
Key Points: Don't assume it's right!

Always check before sending!

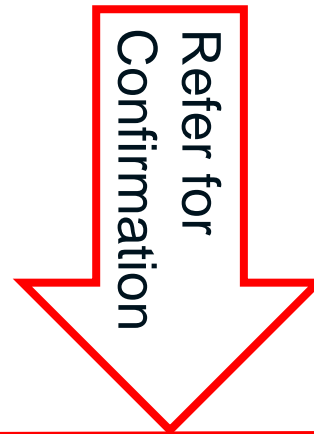
Proficiency Testing NEVER Leaves the Four Walls of the Laboratory



PT Must Never Leave the Four Walls of the Laboratory



PT Must Never Leave the Four Walls of the Laboratory



PT Must Never Leave the Four Walls of the Laboratory



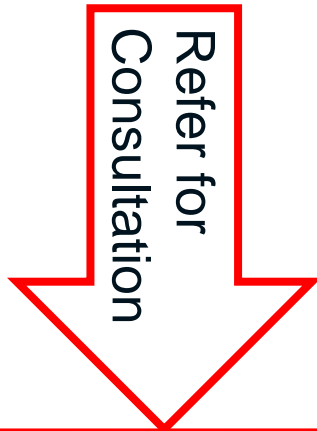
Refer when
test is down

PT Must Never Leave the Four Walls of the Laboratory



Refer for
Correlation Study

PT Must Never Leave the Four Walls of the Laboratory

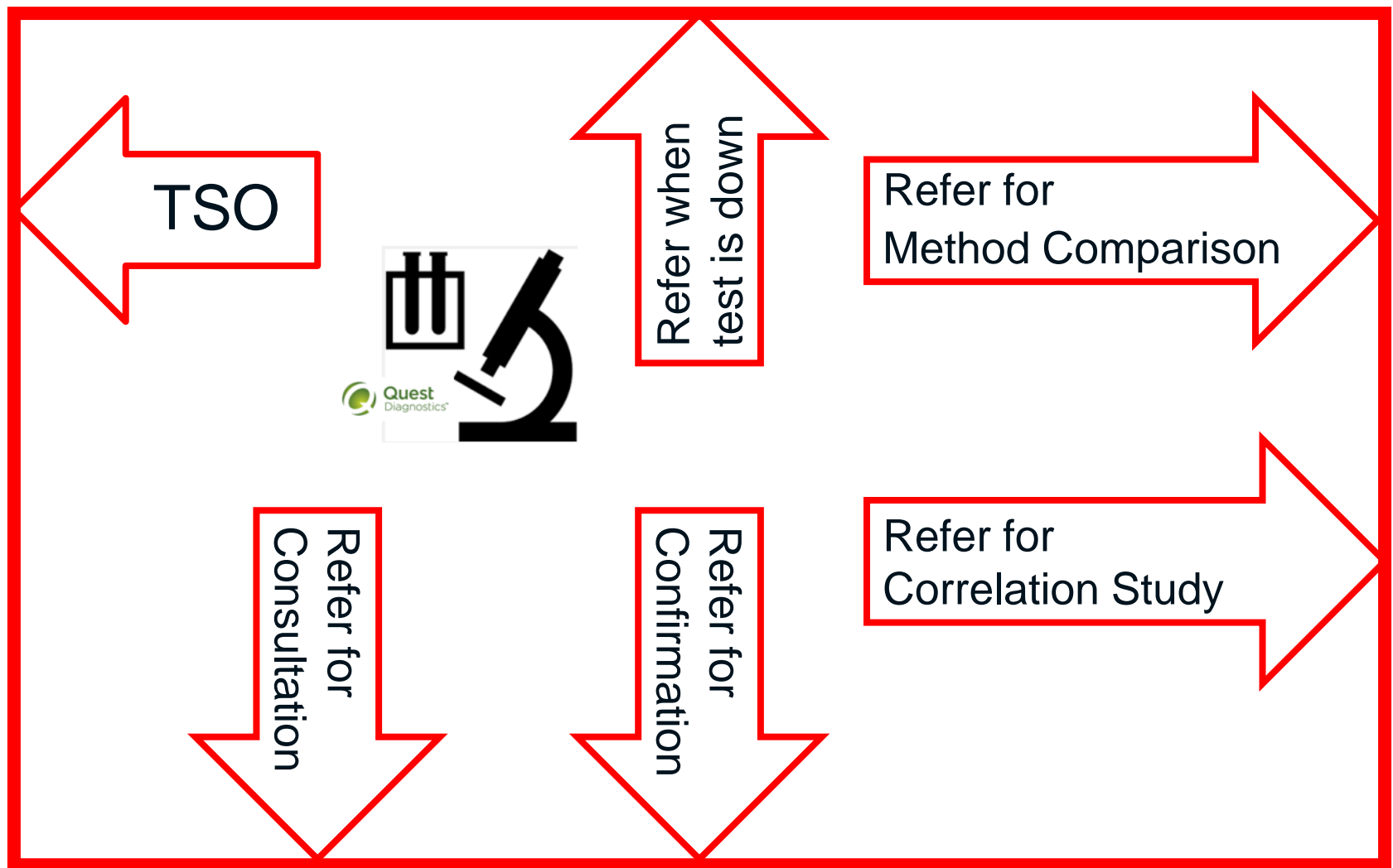


PT Must Never Leave the Four Walls of the Laboratory



Refer for
Method Comparison

NEVER send PT samples outside of the lab for ANY REASON!





Anatomic Pathology Exceptions

- Predictive Markers (HER2, ER/PR and Predictive Markers PM1-5)
 - Immunohistochemical: If the laboratory routinely sends patient slides to an outside laboratory for staining but do your own interpretation, the PT survey slides must also be sent for staining to the same reference lab.
 - Immunohistochemical: If the laboratory routinely accepts unstained slides on patient samples for staining only, it MAY accept unstained PT survey slides for staining.
 - **HER2: The laboratory that interprets HER2 or predictive marker slides stained by another facility must enroll in an accepted PT program and report the results of their interpretation following their usual methods.**
- CMS has ruled that IHC staining is a *process*, not an *analysis* and so the process of staining can be sent out but the **interpretation**, which is the analysis, must be done where the patient interpretations are routinely done.
- The same rule **does not** apply to FISH probes. CMS has ruled that FISH probe application **is analysis** and therefore cannot be referred.

Proficiency Testing Questions / Resources



Why can't I repeat PT testing if it's not in the SOP?

A: Treating PT samples the same as patient samples allows the verification of the accuracy and reliability of a laboratory's testing. PT samples are to be handled exactly like patients with no additional precaution.



What do I do if I know that one analyzer isn't as good as another?

A: Each analyzer and method should produce comparable results every time. If you believe that one analyzer is not providing reliable results – immediately notify your supervisor.



Why can't I run on another analyzer as a check?

A: In our laboratories we perform many different checks to ensure all our instruments are functioning with high accuracy and precision regardless of the analyzer. PT samples should not be given extra care.



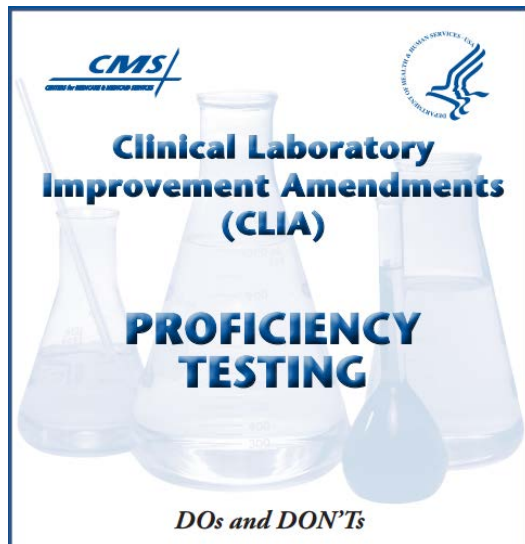
Why can't I have someone else test the PT to confirm my results?

A: The technical SOP for testing patient samples is to be followed when testing PT samples. PT samples are to be handled exactly like patients with no additional precaution.



Proficiency Testing: Resources

- Local QA Department
- CQA, NQA, MRA
- www.cms.hhs.gov/clia 493.801
- CLIA Brochure #8: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/cliabrochure8.pdf>



Consequences for Intentional Referrals



Consequences for Intentional Proficiency Test Referral

- Laboratory may lose its CLIA license for one year (either in the specialty or sub-specialty or for the entire laboratory).
- Laboratory Director may have sanctions imposed (e.g., may not serve as director of any laboratory for two years).
- It is possible that the Owner may not own or operate a laboratory for two years; although CMS will have discretion.
- Fines may be imposed on the laboratory.
- Laboratory may lose ability to bill for Medicare or Medicaid services.
- Bad publicity – Tarnished public image
- Employees may face termination!

Next Steps

NEXT STEPS....

- Read the Quest Diagnostics PT Brochure.
- Take the Quiz and sign the agreement statement.
- If you have any questions, please contact your Supervisor or your BU QA Partner
- **LOOK** for Part 2 of 2016 PT Training coming this fall...

Thank you for your time!

THE LAWS ARE CLEAR

Inter- or Intra-Laboratory communications regarding PT materials or results prior to formal evaluation and Proficiency Test Referral are Prohibited!

Inter- (outside Quest Diagnostics) or
Intra- (within our network of labs)
Laboratory Communications

Any laboratory that the Centers for Medicare and Medicaid Services (CMS) determines has engaged in inter- or intra-laboratory communications regarding an active proficiency test survey before the deadline for submission of data to the proficiency test provider may have its certification revoked for at least one year and/or be subject to civil money penalties.

Proficiency Test Referral

Any laboratory that the Centers for Medicare and Medicaid Services (CMS) determines has intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year and/or be subject to civil money penalties.

For Additional Information
Refer to the PT Standard
Operating Procedures (SOPs)

*“Proficiency Test Handling and
Result Submission”
and*

*“Procedure for Handling
Inappropriate Referral of
Proficiency Material or
Inter- or Intra-Laboratory
Communication of
Proficiency Test Information*

*Report concerns regarding inappropriate practices to either your
Laboratory Director, Supervisor, QA Manager, Compliance
officer or ...*

*Two options to remain anonymous:
CHEQline 1-800-650-9502 or
www.mycompliancereport.com Access code: QDI*



Proficiency Testing Guidelines

*Some of the “Do’s and
Don’ts” when handling
Proficiency Testing
Samples*

DO NOT ENGAGE IN ANY INTER - (WITHIN OUR NETWORK OF LABS) INTRA - (OUTSIDE OF QUEST DIAGNOSTICS) LABORATORY COMMUNICATION ABOUT PROFICIENCY TEST SAMPLE(S) OR THEIR RESULTS UNTIL AFTER FORMAL EVALUATION BY THE PROFICIENCY TEST PROVIDER:

- **Intra- or inter-laboratory communication regarding PT materials or results is STRICTLY prohibited until after the PT provider has formally evaluated the results.** Questions regarding the administration of the PT program or material integrity may be directed to your laboratory director, designee, or PT provider, but communication or discussion with other laboratories concerning PT results is prohibited.
- If another laboratory initiates communication regarding PT results before the survey has been evaluated, the receiving laboratory must not reply or discuss the results with the initiating laboratory. The laboratory staff that received the communication must immediately notify their laboratory director or other laboratory management. The laboratory director or designee must contact Medical Regulatory Affairs.
- If there is a concern about the assay, reagents or test run containing a PT sample, contact the laboratory director for advice; **DO NOT** discuss the issue with another laboratory. The only action that may be taken is one that would have occurred for the patient samples. However, communication with other laboratories is prohibited until after the formal evaluation by the PT provider. Criteria for handling such concerns on patient samples is addressed in the assay SOP.

DO TREAT PT SAMPLES THE SAME AS PATIENT SAMPLES:

- PT samples must be examined, handled, and tested along with the laboratory's regular workload by testing personnel using the laboratory's routine methods. (Some special handling may be required due to the nature of the PT materials, but the PT samples must be treated in the same manner as patient samples to the extent possible.) Exception: **Do not** reflex PT to tests that are performed by an outside laboratory.
- PT samples must not be tested more than once unless a repeat protocol for patient testing is specifically defined by the test SOP and the PT sample meets the repeat criteria.

DO NOT REFLEX PT TO TESTS THAT ARE NOT PERFORMED WITHIN THE TESTING LAB:

- No portion of a PT sample may be referred to another laboratory. Any testing or interpretation that would normally be referred to an outside laboratory for patients **must not** be referred for PT.
- For assays that reflex to a test performed in another laboratory, it is preferred that a separate test code be set up without the reflex.
- If a standard test includes reflex or confirmatory testing that is referred to another laboratory, the laboratory must: NOT order PT testing with that order code; Create a unique order code for PT tests so that PT tests will not be sent to another laboratory for testing.

DO NOT REFER TO, OR ACCEPT FROM, ANOTHER LABORATORY ANY PART OF A PT SAMPLE: CLIA prohibits the referral of any PT material to another laboratory for testing:

The laboratory must not send any PT material to another laboratory for testing. (NOTE: PT material may be shared AFTER the PT provider has formally evaluated results.) If a laboratory receives PT material from another laboratory, site, or location, sequester the material and **do not test**. Immediately notify the Laboratory director or designee to facilitate immediate investigation of the suspect PT.

PT samples should be suspected if:

- "AAB", "AAFP", "ACCU", "ACCUTEST", "ACP", "API", "ASCP", "ASIM", "CAP", "CTS", "EXC", "EXCEL", "MLE", "NY", "PROFICIENCY", "SURVEY", "PENN" or "WSLH" is included in the patient identification.
- A patient name is coded and reflects any of these acronyms (or similar acronyms) and has a two-digit number such as 01, 02, and 03 (e.g., CAP K-01, NYS-02, Survey-03, PENN-04, Proficiency sample)
- The specimen appears to be a commercially prepared product or has the physical characteristics compatible with the consistency of an active PT survey sample.
- The words "Proficiency" or "Survey" appear on the specimen label, requisition or any other document received with the test order.
- You are in the process of participating in a PT survey with a similar name or sample type.