Proficiency Testing

Guidelines for Communication and Handling of Proficiency Material

Initial Training

Quest Diagnostics™

Agenda

- INTRODUCTION
- PURPOSE/SCOPE OF TRAINING
- PT GUIDELINES
- RESPONSIBILITIES
- SUMMARY
- NEXT STEPS

What is Proficiency Testing?

Purpose
- Proficiency Testing (PT) is intended to demonstrate the laboratory's ability to provide accurate and reliable results in its patient testing system.

How is this demonstrated?
- By testing "unknown" samples from an approved PT provider.
- Regulatory agencies such as CMS and the CAP routinely monitor laboratory PT performance.

Scope
- The process incorporates elements in the pre-analytical, analytical, and post-analytical areas.

CLIA – "The Regulation"
Clinical Laboratory Improvement Amendments of 1988

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.

CLIA – "The Regulation"
Clinical Laboratory Improvement Amendments of 1988

493.801(b)(4) Testing of Proficiency Testing Samples

- The laboratory must not send Proficiency Testing samples or portions of samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that the Centers for Medicare and Medicaid Services (CMS) determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certificate revoked for at least one year. Any laboratory that receives proficiency testing from another laboratory must notify CMS of the receipt of those samples.

Clinical Laboratory Improvement Amendments of 1988 (CLIA) - Enforcement Actions for Proficiency Testing Referral

- **On April 29, 2014, the Centers for Medicare and Medicaid Services published the final rule that includes a section entitled (CLIA) - Enforcement Actions for Proficiency Testing Referral**
- The CLIA-related portions of the final rule were effective July 1, 2014.
- Divides sanctions for PT referral into three categories based on the severity and extent of the referrals; also defines "repeat proficiency testing referral" and a new provision that allows it to exempt certain laboratories from the ban on laboratory ownership, on a case-by-case basis, if certain circumstances are met.
  - Category One encompasses the most "serious, egregious violations," consisting of *repeat PT referrals* and cases where a laboratory reports another laboratory's test results as its own. CMS will revoke the laboratory's CLIA certificate for at least one year, ban the owner and operator from owning or operating a CLIA-certified laboratory for at least one year, and possibly impose a Civil Monetary Penalty ("CMP").
  - Category Two includes instances in which a laboratory refers PT samples to a laboratory that operates under a different CLIA number, and while the laboratory reports its own results to the PT program, it receives results from the second laboratory prior to the PT event close date. CMS will suspend or limit the CLIA certificate for less than a year and impose alternative sanctions, including required training of staff.
  - Category Three are those PT referral scenarios in which the referring laboratory does not receive test results prior to the event cut-off date from another laboratory as a result of the PT referral. The laboratory always will be required to pay a CMP and comply with a directed plan of action, including required training of staff.

CMS Interpretations

- "Intentional" in this context is a general intention to act, rather than an intention to violate the prohibition on PT referrals.
- A "repeat proficiency testing referral" is a second instance in which a proficiency testing sample, or a portion of a sample, is referred for any reason to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date.
- Repeat referrals do not include multiple analyses on a referred PT sample or multiple PT samples in the same PT event. A second instance of referral arises when a referral is made from an entirely different set of PT samples from an entirely different PT event sent on a date that is different from the date of the earlier PT event, and a "repeat referral" would take place within the two survey cycles after an initial PT referral (approximately four years), which the Agency believes is a reasonable amount of time for laboratories "to maintain a heightened vigilance" and to thoroughly train all staff to mitigate the chances of a second PT referral.

Consequences for Intentional Proficiency Test Referral

- Laboratory may lose it's 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 (Quest Diagnostics) 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.
- Employees may face termination.
- Bad publicity – Tarnished public image!

Annual Training
Reminds ALL Laboratory Staff That…

Federal Regulations require that laboratories:

- DO NOT Accept or Test PT material FROM another laboratory
- DO NOT Refer any portion of a PT sample TO another laboratory
- DO NOT Communicate PT results or information on active PT surveys within or outside of Quest Diagnostics prior to formal report from provider
- DO to the extent possible, test PT samples the same as patient samples UNLESS a patient sample is referred

Annual Training Is Important Because…

- Confusion still exists for some employees
- Accidental referrals to other laboratories still occur
- Some Quest Diagnostics laboratories continue to receive PT from clients

What is the Scope of this PT Training

- Applies to all personnel involved in handling any aspect of Proficiency Testing including employees that:
  - Pick-up or Transport samples (Quest Diagnostics couriers - *training limited to appropriate scenarios*)
  - Receive or log-in samples
  - Testing samples (including loading of samples onto instruments)
  - Report results of proficiency testing samples
  - Refer patient samples for testing
  - Communicate with clients
- **Excludes:** PT that is specifically addressed in the "*External Proficiency Testing for Gynecologic Cytology*" and the *"Proficiency Test Handling and Results Submission for Point of Care Testing Sites"* SOPs

Proficiency Testing Guidelines

DO NOT ACCEPT or TEST PT Materials from Another Laboratory

DO NOT ACCEPT or TEST
PT Materials from Another Laboratory

PT samples should be suspected if:

- "AAB", "AAFP", "ACCU", "ACCUTEST", "ACP", "API", "ASCP", "ASIM", "CAP", "CTS", "EXC", "EXCEL", "MLE", "NY", "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 the QA Account

Contact your supervisor or the QA Department

DO NOT ACCEPT or TEST
PT Materials from Another Laboratory

- The laboratory must have a process to detect suspect inappropriate PT referral from another laboratory.
- If the laboratory receives Suspect PT material from another lab:

DO NOT PROCESS

How do these samples come into our laboratories?

- Directly from clients (via mail, courier pick up, FedEx)
- Clients dropping off samples at a PSC
- From other Quest Diagnostics facilities
- Remote Accessioning (e.g., In Office Phlebotomy sites, remote accessioning centers)

How do we stop these samples from entering the normal workflow?

Couriers can stop samples by:

- Identifying bags / paperwork / samples that may be suspect PT from a client or another laboratory.
- If there are samples in non-Quest bag; ask the client if the samples are meant for pick-up.
- If there are samples in a Quest bag and you can see any of the terms on either the samples or the paperwork; ask the client if the samples are intended for pick-up.
- If client says sample(s) is intended for pick-up, document client response.
- Upon arrival at the laboratory notify a supervisor of the suspect samples.

Examples of suspect PT materials

How do we stop these samples from entering the normal workflow?

Specimen Accessioning can stop samples by:

- Identifying test orders that may be suspect PT from another laboratory

Remote Accessioning can stop samples by:

- Identifying suspect PT samples before logging them into Care360 (or other system) and by not sending them into the testing laboratory

Testing Personnel can stop samples by:

- Identifying suspect PT from another laboratory by name, sample type or results

Testing Referrals and Redirects: Temporary or Permanent

Notify the QA Department **immediately** when a test is being temporarily or permanently referred or redirected to another laboratory.

PT Tests MUST NOT be accessioned for tests that are temporarily or permanently referred or redirected to another laboratory; even if you think the test will be back up by end of day. Once testing is back up in-house you may accession.

- Remember to take down profile test codes for PT that contain even one component that is temporarily or permanently referred or redirected to another lab.
- Remember to take down reflex codes (initial or reflexed to test codes) that are temporarily or permanently referred or redirected to another laboratory.

Emergency Referrals or Redirects:

- FOR ANY test that is temporarily referred or redirected, you MUST identify any active PT.
- Actions must be taken to stop any PT in process from being accidently referred or redirected to another laboratory:
  - Sequester the PT specimens, report as TNP to prevent PT from being accidently sent to another laboratory, notify your manager and the QA department.

Things to consider when sharing a UCI:

Existing benefits may actually lead to inadvertent PT Referral

- In some cases, when specimens are sent from one lab to another on the same UCI there is no need to re-accession specimens which by-pass one of the opportunities for identifying PT referrals at accessioning.
- It is critical to review worklists when sending or receiving pre-accessioned loads from another laboratory in order to help identify test orders that may have suspect PT.

Ensure that PT Results are not shared prior to formal review

- Actions should be taken to limit access to QA accounts to prevent employees from viewing PT results from another lab on the same UCI.

PT should NEVER be accessioned for tests that are temporarily or permanently referred to another laboratory; regardless of how long the test will be down.

- Remember to NOT USE profile or reflex codes that have a component or components that are temporarily or permanently referred to another laboratory.

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What Would You Do?

Case Scenarios: PT Received from Another Laboratory

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Scenario - Referring Laboratory

- Assay is temporarily unavailable.
- The decision is made to refer/redirect patient samples to another laboratory.
- As you are preparing the printed load list/worklist OR as you are building your shipping manifest, you identify an accession or sample as suspect PT.

What would you do?

-  **STOP!**
- Pull the samples from the load; sequester the samples.
- Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Scenario - Receiving Laboratory

- You are receiving specimens from another laboratory that have already been accessioned and do not require re-accessioning.
- As you are reviewing the load list/worklist or the shipping manifest, OR while changing the order, you identify an accession or sample as suspect PT.

What would you do?

-  **STOP!**
- Pull the samples from the load; sequester the samples.
- Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Scenario

When picking up or sorting specimens you notice…

- **Paperwork: Not a requisition. WSLH PT Shipping Request Form**
- **Not a specimen bag, zip-lock bag only**
- **Suspect Vials/Containers**
- **Vials Labeled: 2014 PBC1-5**

What would you do?

- **STOP!**
- For Couriers: If the client's office is **open**, ask the office manager about the intent to send the specimen(s) in question to Quest.
- For Couriers: If the client's office is **not open**, then deliver the suspect specimen(s) to Quest and notify a Supervisor who must notify the QA department.
- For Accessioning: Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Scenario

- You work in microbiology and your department accepts blood agar plates from clients. When reviewing the bar code on a plate from the client you notice MY-09.

What would you do?

- **STOP!** Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Reminder:

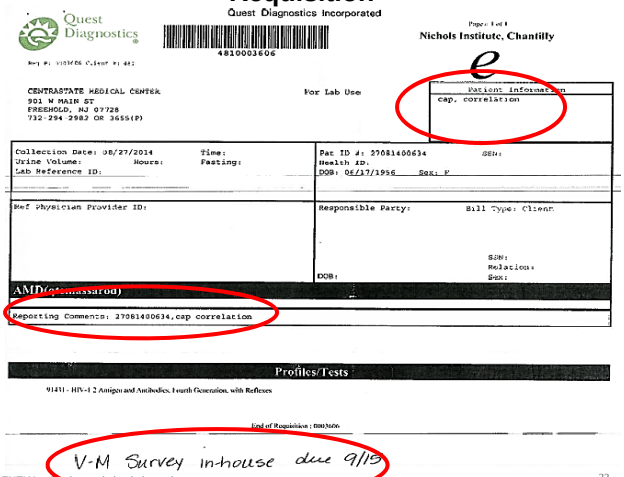
Scenario

- A sample labeled “correlation” comes into your lab from another lab.
- The requisition is also labeled with the identifier “correlation”
- Notes: V-M Survey in house due 9/15
- The test ordered is either performed in-house or is one that you refer to another laboratory for testing.

Requisition and Specimen

Note multiple clues!

Requisition


Quest Diagnostics Incorporated

Nichols Institute, Chantilly

4810003606

CENTRASTATE MEDICAL CENTER
901 W MAIN ST
FREEHOLD, NJ 07728
732-294-2982 OR 3655(P)

For Lab Use

cap. correlation

Collection Date: 08/27/2014 Time:
Urine Volume: Hours: Fasting:
Lab Reference ID:

Pat ID #: 27081400634
Health ID.
DOB: 06/17/1956 Sex: F

Ref Physician Provider ID:

Responsible Party: Bill Type: Client

SSN:
Relation:
Sex:

DOB:

AMD(

Reporting Comments: 27081400634,cap correlation

Profiles/Tests

91431 - HIV-1,2 Antigen and Antibodies, Fourth Generation, with Reflexes

End of Requisition : 0003606

V-M Survey in-house due 9/15

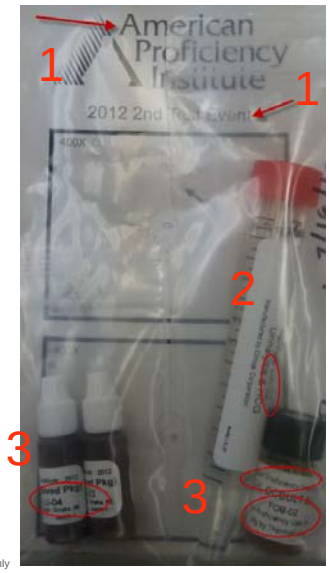
Specimen

What would you do?

STOP! Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Scenario:

When sorting specimens instead of a patient name you notice…



1. **Paperwork labeled: American Proficiency Institute, 2nd Test Event**
2. **Suspect Vials/Containers**
3. **Labeling: UA-02, FOB-02, Proficiency**

What would you do?

STOP! Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Scenario

- When accessioning a sample you notice instead of a patient name, the sample is labeled as “Urinalysis UR12-2-1, For Proficiency Use Only”.

Scenario

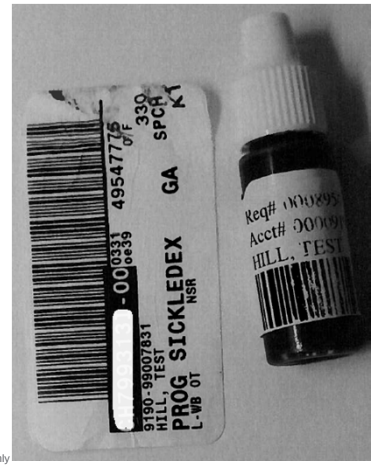
- In addition to the samples, a PT Survey Response sheet was included in the specimen bag.

What would you do?

STOP! Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Scenario

- When preparing a sample for testing you notice that the sample TYPE is unusual…it is not a tube….it is not a swab…it not a pour off tube….it is a small vial.

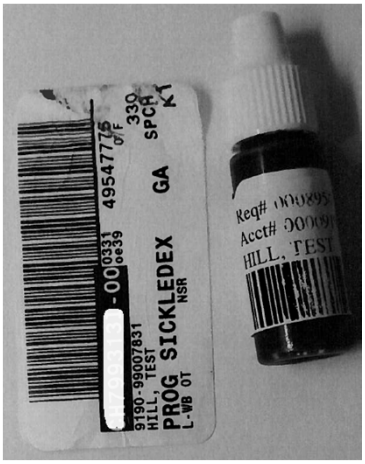


What would you do?

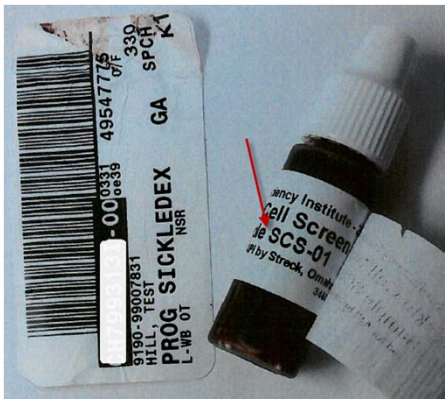
STOP! Immediately notify your Supervisor and the QA Department to begin an internal investigation.

Investigation Found:

Suspicious Vial



Peeled Back Labels



Scenario

- When reading information on the requisition you notice the patient's name is PENN, JACK. What would you do?
- **PROCESS THE SAMPLE!** While the sample has the word PENN on it, the name does not have a two digit number after it. A suspect PT sample would most likely be PENN-01 or PENN-03.

DO NOT REFER PT Materials To Another Laboratory

DO NOT REFER
Any Portion of a PT Sample to Another Laboratory

- **NEVER** send any portion of a PT sample to another laboratory. This is considered PT referral and will cause serious actions to be taken against your laboratory and your laboratory director and possibly Quest Diagnostics as a corporation.

DO NOT REFER
Any Portion of a PT Sample to Another Laboratory

- **If a test or instrument is down:**
  - DO NOT ACCESSION THE PT
  - If already accessioned, CANCEL ANY PT TEST(S) that may be on the worklist.
  - NOTIFY QA that testing on PT material will not be done.
  - QA must request take down of any PT custom panel or reflex code that includes the test being referred
- **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 test so that PT samples will not accidently be sent to another laboratory for reflex or confirmation.
  - Indicate on the proficiency test result form that the sample would be referred and therefore was not tested.
  - **Examples:** HIV Western Blot; Lyme Western Blot; Toxicology tests for GCMS; IgG or IgM tests

How do we stop PT from being referred to another laboratory?

Referral personnel can stop samples by:

- Identifying and stopping test orders that may be suspect proficiency testing before they are accidentally sent to another laboratory.
- Checking the names on your batch or work lists to ensure they do not contain suspect PT Acronyms.

QA can stop samples by:

- Making sure PT order codes do NOT contain automatic reflex codes to another laboratory.
- Routinely reviewing test menus and PT order codes whenever tests are added or removed from the laboratory test offering.
- Not using panels or profiles for accessioning PT surveys
- Never accessioning a PT sample even if a test is only temporarily down (i.e., test is referred or redirected to another lab for several days pending a reagent.) DO NOT ACCESSION the PT sample.

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What Would You Do?

Case Scenarios: PT Accidentally Referred to Another Laboratory

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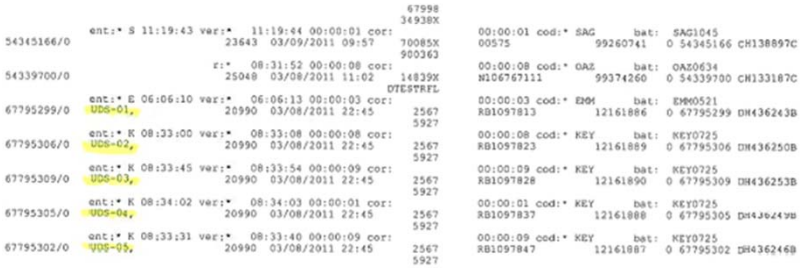
Scenario

- Your lab routinely performs Drug Screening however, GCMS confirmation is not performed in your lab. Positive patient results generate an automatic reflex for referral to another lab for the confirmatory testing. When reviewing the worklist of specimens to be sent to another laboratory for confirmation you notice UDS-04 and UDS-05.



```
                                                                  67998
                                                                  34938X
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54345166/0                     23643  03/09/2011 09:57    70085X         00575            99260741   0 54345166 CH138897C
                                                          900363
                         r:*   08:31:52 00:00:08 cor:                    00:00:08 cod:* OAZ      bat:  OAZ0634
54339700/0                     25048  03/08/2011 11:02    14839X         N106767111       99374260   0 54339700 CH133187C
                                                          DTESTRFL
      ent:* E 06:06:10 ver:*   06:06:13 00:00:03 cor:                    00:00:03 cod:* EMM      bat:  EMM0521
67795299/0  UDS-01,            20990  03/08/2011 22:45     2567         RB1097813        12161886   0 67795299 DH436243B
                                                           5927
      ent:* K 08:33:00 ver:*   08:33:08 00:00:08 cor:                    00:00:08 cod:* KEY      bat:  KEY0725
67795306/0  UDS-02,            20990  03/08/2011 22:45     2567         RB1097823        12161889   0 67795306 DH436250B
                                                           5927
      ent:* K 08:33:45 ver:*   08:33:54 00:00:09 cor:                    00:00:09 cod:* KEY      bat:  KEY0725
67795309/0  UDS-03,            20990  03/08/2011 22:45     2567         RB1097828        12161890   0 67795309 DH436253B
                                                           5927
      ent:* K 08:34:02 ver:*   08:34:03 00:00:01 cor:                    00:00:01 cod:* KEY      bat:  KEY0725
67795305/0  UDS-04,            20990  03/08/2011 22:45     2567         RB1097837        12161888   0 67795305 DH436249B
                                                           5927
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67795302/0  UDS-05,            20990  03/08/2011 22:45     2567         RB1097847        12161887   0 67795302 DH436246B
                                                           5927
```


What would you do?

STOP! Notify your Supervisor immediately.

- **Prevention Tip:** Be sure that PT samples are not accessioned into the LIS using an order code that automatically reflexes testing to another laboratory.

DO NOT COMMUNICATE PT Information With Another Laboratory

DO NOT COMMUNICATE
PT Results or Information on Active PT

- **Inter- (outside of Quest Diagnostics) or intra- (within our network of labs) laboratory communication regarding PT materials or results is STRICTLY prohibited until 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 or designee, or PT provider, but communication or discussion with other laboratories concerning PT results is prohibited.

DO NOT COMMUNICATE
PT Results or Information on Active PT

- If another laboratory initiates communication regarding PT results before the survey has been formally 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 Supervisor, QA Department, Laboratory Director or other laboratory management.

    AND
  - Notify Corporate Medical Regulatory Affairs
- If there is a concern about the assay, reagents or run containing a PT sample, contact your Supervisor for advice; DO NOT discuss via phone, email or in person with another laboratory.

DO NOT COMMUNICATE
PT Results or Information on Active PT

- If you are employed at more than one laboratory you may not participate in the same active proficiency testing at both facilities.
  - Performing the same proficiency activity at multiple laboratory facilities is a violation of CLIA and accrediting institution requirements, and may result in loss of the employee's own licensure and the licensure of both laboratory facilities.
- The employee is required to work with their supervisors at both facilities to ensure that:

1) Intra- or inter-laboratory communication does not occur;
2) The employee is not actively participating in the same PT surveys at both facilities; and
3) The employee is participating in PT at each facility as required without overlap.

What Would You Do?

Case Scenarios: Inappropriate PT Communication

What would you do?

- The results of PT for a particular analyte indicate that there may be an issue with the reagent lot. The same issue is NOT noticed with the patient samples and the reagent lot passed lot-to-lot validation. You have a concern that other labs at Quest Diagnostics are using the same reagent lot for their patient testing, but the only evidence you have to share is the PT data. What would you do?

- **STOP!** Contact your Supervisor or Laboratory Director or Designee to discuss your concerns.
  - **Reminder:** NO discussion of PT results with ANY laboratory may take place before formal evaluation is completed by the PT provider.

What would you do?

- You call a client to give them a critical value on a result. When you tell the client the patient name and value, they say “oh..that’s okay…that’s just our PT samples that we sent to you.” What would you do?

- **STOP!** Do not communicate the results. Contact your Supervisor, QA Department and Laboratory Director or Designee immediately.

What would you do?

- You are at your workstation and you overhear another employee discussing proficiency test results. You suspect the employee may be speaking with someone from another lab. What would you do?

- **STOP!** Immediately contact either your Supervisor, QA Department, Laboratory Director or Designee.

  - **Reminder:** You may also call the **CHEQline** so that the issue can be investigated (1-800-650-9502).

What would you do?

- A client calls requesting Creatinine test results. You look up the results and see that the patient's name contains an acronym that indicates suspect PT. The client confirms it is a PT sample; but routinely sends this test to Quest and is only using the result in the calculation for other urine tests in the PT survey. What would you do?

STOP! Do not communicate the results. Contact your Supervisor, QA Department and Laboratory Director or Designee immediately.

- **Reminder:** NO discussion of PT results with ANY laboratory may take place before formal evaluation is completed by the PT provider.

What would you do?

- You are employed at both laboratory A and laboratory B. You have already performed the current / active PT at laboratory A and are aware that laboratory B is also participating in the current / active survey event. What would you do?

STOP! Do not discuss the results of the current/ active survey. Notify your supervisors immediately of your participation and work with them to ensure that intra- and inter-laboratory communication does not occur.

DO TREAT PT In The Same Manner as Patient Samples

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DO
TEST PT Samples the Same as Patient Samples

- **Examine, handle, and test PT samples along with the laboratory's regular workload, by the same 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 is do not refer any portion of a PT sample to another laboratory.
- **DO** test PT sample as defined in the test SOP including repeat criteria.
- **DO** rotate PT testing among all staff who routinely perform the patient testing (e.g., each survey should not always be performed by the same person).
- **DO** perform calibration and quality control as indicated in the assay protocol.

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EXCEPTIONS
To Treating PT the Same as Patient Samples

Slides for Pathologist Review

- **For a patient:** When a slide requires pathologist review AND the pathologist reads the slide at a site outside of your laboratory, the slide is sent out for review as appropriate.
- **For a proficiency testing sample**.  The pathologist must review the slide within the four walls of your laboratory.

Reflex and Confirmatory Testing

- **For a patient:** When a test requires a reflex or confirmation to an outside laboratory, it is sent out for testing as appropriate.
- **For a proficiency testing sample**.  Do not refer any part of a proficiency sample, or data for review, to another laboratory even if your would normally do so for patients. This includes sending to another Quest Diagnostics laboratory.

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What Would You Do?

Case Scenarios: Treat PT the Same as Patients

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What would you do?

- You laboratory performs hemoglobinopathy evaluations. For difficult cases, the routine practice in your laboratory is to refer the chromatographs and your interpretation of positive results for consultative review to either another laboratory or an outside consultant. How would you treat the difficult case if it was a proficiency test?
- **STOP!** It is prohibited to refer any portion or data from a PT event prior to formal evaluation by the PT provider. Do not contact outside consultants even if that is the process for patients.
  - **Reminder:** This is an example of the EXCEPTION to treating PT like a patient sample.

What would you do?

- The AP Department receives their IHC PT survey. The slide is stained and ready for interpretation by the pathologist. The next pathologist in the PT rotation list is not in your laboratory that day, but is working at the Quest-managed hospital laboratory across town. Should you send the slide to the pathologist?
- **STOP!** The pathologist must review the slide within the four walls of your laboratory. Do not send PT samples to a pathologist sitting at a location outside of your laboratory, even if that is the process for handling routine patient slides.
  - **Reminder:** This is an example of the EXCEPTION to treating PT like a patient sample.

What would you do?

- PT samples arrive in the department at the beginning of your shift. You would like to run them immediately in order to "get them out of the way" before patient samples start arriving. What would you do?
- Wait until patient samples arrive and load them along with patient samples for testing.
  - **Exception:** In a small facility, infrequent testing may necessitate the running of PT samples without patient specimens to ensure that the PT test results are reported on time.

What would you do?

- You just received a new survey that includes CBC testing. Your supervisor tells you to run them with the next load which is set to run on Instrument A. You think Instrument B gives better results than Instrument A. Which instrument would you use for PT testing?
- Instrument A
  - **Reminder:** PT samples must be examined, handled and tested along with the laboratory's regular workload, by the same testing personnel, using the laboratory's routine methods.

Responsibilities

What are the Responsibilities of the Laboratory Director (CLIA License Holder)?

- Ensuring laboratory enrollment in PT programs as required by Quest Diagnostics and regulatory agencies.
- Ensuring that PT samples or data are not inappropriately accepted, tested, referred or communicated.
- Providing the investigation and notification as appropriate to Corporate Medical Regulatory Affairs, CMS and CAP of any suspected or confirmed referral of inappropriate PT material referral or improper PT inter- or intra-laboratory communication.
- Contacting a referring laboratory's director if accidental referral occurs.

What are the Responsibilities for Supervisors?

- Implementing the process in the department(s) or laboratory for which he/she is responsible.
- Ensuring documented training in his/her department(s) for all employees including new hires and those returning from FMLA (within 30 days of hire / return AND prior to handling PT samples).
- Reviewing PT results, instrument/method information and test units for accuracy.
- Notifying QA of changes in Test Menu: (New Tests, Send-outs, Tests Down and Deleted Tests). Pulling active PT samples during assay downtime.
- Rotating PT testing among personnel and instruments.
- When Suspect PT Samples are Identified:
  - Initiating a “Suspect Proficiency Sample” form.
  - Sequestering suspect material.
  - Submitting “Suspect Proficiency Sample” form to QA Department immediately.

What are the Responsibilities for Specimen Processing Personnel?

- Identifying test orders that contain names, numbers or acronyms that suggest suspect proficiency testing from another laboratory.
- Stopping suspect PT samples from entering the normal work flow.

What are the Responsibilities for Testing Personnel?

- Testing PT material in the same manner as patient samples
  - **Reminder** DO NOT REFER any portion of a PT sample to another laboratory until after formal evaluation.
- Documenting performance of all steps in the proficiency testing process.
- Processing PT specimens with normal workflow (if not, document why).
- Utilizing the same repeat/dilution protocols and same calibration and quality control frequency.
- Signing Attestation Form (or copy of completed form).
- Identifying suspect proficiency testing materials.
- Notifying supervisor if they have participated in the current PT survey at another laboratory.

What are the Responsibilities for Client Service Personnel?

- Using reasonable efforts to identify, through visual recognition of patient information (verbal or electronic) any sample that may be a proficiency test sample.
- Notifying their Supervisor immediately if at any time, when clarifying a test order or discussing a result, the client states or implies that the sample submitted is a proficiency sample.

What are the Responsibilities for Referral Personnel?

- Identifying and Stopping test orders that may be suspect proficiency testing before being accidentally sent to another laboratory.
- Notifying their supervisor immediately if identified.

What are the Responsibilities of the Quality Assurance Department?

- Monitoring of PT Training
- Managing of the PT Process (Enrollment, Accessioning, Reporting and Reviewing Evaluations)
- Ensuring PT order codes DO NOT contain reflex testing referred to another laboratory or tests that refer patient testing to another laboratory; even if referral or redirection of samples is temporary.
- Ensure when tests are referred either temporarily or permanently that PT is NOT accessioned; even if downtime is only for a day.
- Providing oversight of the RRL, POCT and Hospital PT Programs
- Ensuring APA is performed as required
- Training employees on LOCAL naming convention for PT material
- When Suspect PT Samples are Identified:
  - Sequestering suspect material
  - Completing the “Suspect Proficiency Sample” form
  - Managing the reporting of and responses to Suspect PT events (notifying Corporate Medical Regulatory Affairs)

Summary of General Requirements

Summary of General Requirements

- DO NOT Accept or Test PT material FROM another laboratory
- DO NOT Refer any portion of a PT sample TO another laboratory
- DO NOT Communicate PT results or information on active PT surveys within or outside of Quest Diagnostics prior to formal report from provider

- DO Test PT samples the same as patient samples
  - Note: If a Standard Test includes Reflex or Confirmatory Testing that is routinely referred to another laboratory, DO NOT use the standard code to order the PT test in order to prevent accidental referral of PT tests to another laboratory.
  - Indicate on the proficiency test result form that the sample(s) would be referred.

Corrective Action for Non-compliance

- The following may result in corrective action up to and including termination:
  - Knowingly **referring** a PT sample to another laboratory
  - Knowingly **accepting** a PT sample from another laboratory
  - Knowingly **engaging in any inter- or intra-laboratory communications** about proficiency testing sample(s) before formal evaluation of results by the proficiency testing provider.
  - Failure to fully cooperate and be truthful in any investigation regarding suspected non-compliance with this policy may result in corrective action up to and including termination.

NEXT STEPS….

- Review Brochure / Poster on the Proficiency Testing Guidelines - *Do's and Don'ts when handling Proficiency Testing Samples*
- Take the Quiz and sign the Verification form
- If you have any questions, please contact your Supervisor or your Quality Assurance Department

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.

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

If these items are seen anywhere on the requisition, sample, or electronic record, OR if there is any reason to suspect that the sample is a proficiency test sample (e.g., sample type, integrity, or result)

DO NOT TEST
DO NOT REPORT (electronically or verbally)
CONTACT YOUR SUPERVISOR

Laboratory Director _____Date_____

Quest Diagnostics