# A Failed PT Round Is an Investigation, Not a Score

The PT report says unacceptable, the next round passes, and both pages go in the binder. Assessors look for the written investigation that belongs between them, and cite the lab when it's missing.

**Brandon Holland**, Marketing & Operations Digital Solutions Architect

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IN BRIEF

What should a lab do after a failed proficiency testing round? Investigate the possible causes, decide whether reported results are affected, and document the review and the decision. Under CLIA and TNI, the record also shows a remedial action. Passing the next round can show that a fix worked, but it does not replace the investigation.

### Key takeaways

- A missing PT investigation can be cited years later. One 2026 survey cited an unacceptable result from 2023.
- Under CLIA and TNI, the PT record always shows a remedial action. Under ISO/IEC 17025, "no action" with a reason can stand.
- Start with clerical errors and the PT item, then check the run and the method, then the provider's assigned value.
- Check the results reported between the PT run and the score. What caused the miss tells you which ones are in question.
- CMS proposes to end the six-month reinstatement wait after PT sanctions. The documented investigation stays required.

The Q3 proficiency testing report comes back with one analyte flagged unacceptable. The next round goes out, and when Q4 comes back clean, the supervisor writes “re-run Q4, passed” on the Q3 page. Both pages go in the binder, and the lab moves on.

At the next survey, the assessor opens that binder, reads both pages and asks to see the investigation.

Most labs can produce their scores, whether they keep them in a binder or in a laboratory information management system. The written investigation is what assessors find missing. A failed PT result needs a documented review of possible causes and a recorded decision. In a CLIA or TNI lab, that decision always includes a remedial action, even when the fix is small.

## What counts as a proficiency testing failure?

Each scheme draws the line in a different place, and the table puts CLIA’s proficiency testing rules beside TNI’s and ISO/IEC 17025’s.

| SCHEME | WHAT FAILS | WHAT IT TRIGGERS | WHO SEES IT |
|---|---|---|---|
| CLIA | Under 80 percent in an event for most specialties, 100 percent for ABO and D typing, antibody detection and compatibility testing. A missed event scores 0. | Remedial action, documented and kept two years | CMS surveyors |
| TNI / NELAP | Fewer than two acceptable studies in the most recent three, per field. A missed study counts as failed. | A documented root cause investigation and corrective action | Your accreditation body, which gets your results from the provider |
| ISO/IEC 17025, with ISO/IEC 17043 schemes | A score past your acceptance criteria, normally the provider's, such as a z-score of 3 or more | An evaluation in your nonconformity procedure, documented even when you take no action | Your accreditation body |

If CAP accredits you, read CAP's proficiency testing requirements alongside CLIA's. For environmental labs, we cover TNI's pass criteria in detail.

**All three schemes require a written investigation after a failure.**

## Why is passing the next round not the end of it?

Passing the next round doesn't explain the failed one. The Q4 pass tells you the method worked in Q4. It says nothing about why Q3 failed, or whether anything you reported between the two rounds was wrong.

Eurachem's guidance on poor PT performance is direct about this. A lab "should acknowledge it, carry out an investigation and document a review of possible causes, even if it decides not to take any specific action."

That last option is open to an ISO/IEC 17025 lab, which sets its own criteria for when to act. CLIA and TNI leave it closed. Every CLIA specialty section puts it plainly for any unacceptable analyte or unsatisfactory

event: “Remedial action must be taken and documented.” TNI asks for the root cause and a corrective action. In those labs, the record always shows an action. For a clerical cause, it can be as small as fixing the transcription step.

We would rather read two short paragraphs on the miss and the response than a clean next round with nothing behind it. In a 17025 lab, the response can be “no action, here is why.” In a CLIA or TNI lab, it names the remedial action.

> NOTE
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> Write your triggers into policy before you need them. In z-score schemes, the common convention makes a single 2.5 a warning signal: record it and watch the trend. Investigate when questionable scores repeat on the same measurement or consecutive scores carry the same bias sign. CLIA grades by percent per event, and every unacceptable result there needs documented remedial action.

## What should the investigation look at, in what order?

Start with the cheapest explanation and work toward the most expensive one. First, check whether the PT report explains the result, and confirm it shows what you submitted.

Then look for clerical errors. Eurachem calls finding them “an important first step of an investigation,” and its first example shows why. A medical lab’s tumor-marker PT results were off by 20 percent while its daily controls were fine. An IT system update had introduced a wrong unit conversion factor for PT results. Patient results used a different unit, so none were affected.

Check the PT item next, then the run and the method. In a second example, a food lab undercounted Listeria because the analyst used an out-of-date procedure, and the lab’s 5 Whys ended at the workload of the person in charge of document control. Look at the scheme last. An assigned value with too much uncertainty can score a lab unsatisfactory for reasons outside the lab, and that finding goes in the record too.

For the Q3 analyte in that binder, check these ten points:

- The report matches what you submitted
- Clerical: transcription, decimals, units, item mix-ups
- The PT item's condition, storage and handling
- The retained item re-measured
- The run: raw data, internal QC, calibration, reagents, analyst, procedure version
- The trend: earlier rounds and same-sign bias
- The scheme: matrix match, the assigned value and its uncertainty
- Results reported since the PT item ran
- Remedial action and proof it worked, or why none (17025 only)
- The decision, signed and dated by a supervisor or director

## What do assessors cite after a PT failure?

Assessors cite the missing record, and they can cite it years after the event. A CMS Form 2567 for an Illinois laboratory, from a survey completed April 14, 2026, reads like the binder from the opening.

The surveyor quoted the lab's own policy, which required a root cause analysis and documented corrective actions. Then the surveyor wrote the finding under tag D5221: "Review of CAP PT records revealed a lack of corrective action documentation for one of one unacceptable PT performance."

The event was in 2023, and the citation came in 2026. Under tag D6091, the same form found that only testing personnel had reviewed two of five PT events. In 2025, ASCLS wrote that "PT performance and review is a supervisory duty that often gets pushed to the back burner."

Two things changed in 2026. Neither one changes what goes in the record. In July, CAP told laboratories that some international PT shipments would arrive late or not at all. Under CLIA, a missed event still needs a documented check of accuracy. In October, CMS proposed to end the six-month reinstatement wait after PT sanctions. It called the wait "more punitive than motivational" and left the documentation duties as they are.

PROFICIENCY TESTING IN 2026

**Jul 7, 2026**

CAP reports conflict and airspace restrictions disrupting PT/EQA shipments to parts of the Middle East, Africa and South Asia.

**Jul 10, 2026**

CAP lists programs whose materials expired before shipment and tells labs to ask about alternative assessment.

**Oct 8, 2026**

CMS publishes proposed rule CMS-3478-P, which would remove the six-month minimum before reinstatement.

**Dec 7, 2026**

Comments on the proposed rule close.

## Which reported results are affected, and do you tell the customer?

What you found decides which reported results are in question. If the cause was a typo on the PT submission, the results you reported weren't touched, and the record should say why. If the cause was in the method, the instrument or the procedure version, every result run under that cause is in question.

TNI asks labs to notify customers in writing if results may have been affected, under a policy that sets the time frame. ISO/IEC 17025 asks for an evaluation of significance, "including an impact analysis on previous results," and a decision on acceptability. Then, "where necessary, the customer is notified and work is recalled."

CLIA has no PT lookback rule. What you owe depends on what you found. Under 493.1445(e)(4), the director makes sure an approved corrective action plan is followed, and the specialty sections keep the remedial

action on file for two years. When the investigation finds errors in reported patient results, 493.1291(k) says to “Promptly notify the authorized person ordering the test” and “Issue corrected reports promptly.”

Put the list of results you checked on the same corrective action record as the cause, so the assessor reads one record.

**Write down which results you checked, even when the answer is none.**

## Would your last PT failure pass this check?

Pull your last unacceptable PT result. The record should show a written review of possible causes, the decision and the reported results you checked. Under CLIA or TNI, it should also name the remedial action. A supervisor or director should sign and date it. If only the analyst signed, that’s the D6091 finding from the Illinois form.

Here’s an example half page for a clerical cause, modeled on Eurachem’s unit-conversion case:

- **Result:** tumor marker, Q3 event, unacceptable, 20 percent off the assigned value.
- **Causes reviewed:** daily controls in range, calibration and reagent lots unchanged, and the retained item agrees once the units are converted correctly.
- **Cause:** a system update changed the unit conversion factor for PT results only.
- **Results checked:** patient results are reported in a different unit, so none were affected.
- **Remedial action:** the factor corrected, and a second person checks units before each PT submission.
- **Check:** the Q4 event went through the corrected step and passed.
- **Signed:** the laboratory director, with the date.

If a page like this is missing, start it now, while the people who ran the sample still remember the day.

## How does a LIMS help with a PT investigation?

A LIMS helps most when the PT run is on the record before the score arrives.

> **How LabLynx handles this**
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> Most of a PT investigation is reconstructing the day the PT item ran. In LabLynx LIMS, a PT sample runs through the same workflow as your patient or routine samples, and a flag only marks it for review. The method version, instrument, analyst and calibration state are on the record when the score arrives. A failed PT event can open a corrective action linked to the PT sample and the method. A query by method or instrument pulls the results reported since that run.
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> If you want a second reader before your next survey, our compliance team reviews PT investigation records against what assessors cite.

## Frequently asked questions

### What counts as a proficiency testing failure under CLIA?

Under 42 CFR 493.2, unsatisfactory performance means missing the minimum score for an analyte, test, subspecialty or specialty in one testing event. For most specialties the minimum is 80 percent. ABO group and D typing, antibody detection and compatibility testing need 100 percent. A missed event scores 0. Missing on the same analyte in two consecutive events, or two of three, is unsuccessful participation.

### Do I have to investigate a PT failure if the next round passed?

Yes. Under CLIA, any unacceptable analyte or unsatisfactory event needs remedial action, documented and kept for two years, so the record always shows an action, even a small one. TNI requires a documented root cause investigation and corrective action. Under ISO/IEC 17025, a lab may decide no specific action is needed, and it documents that evaluation. The passing round shows whether a fix worked.

### What should a PT investigation record contain?

The record holds the PT result and the scheme, each possible cause reviewed with its evidence, and the decision. It lists the reported results considered and whether any were affected. Under CLIA and TNI, it

names the remedial action, its owner and the check that it worked. A 17025 no-action decision states its reason instead. The authorized reviewer signs and dates it.

**What if the PT sample was not commutable with routine samples?**

That can be a real cause. Eurachem lists a matrix difference between the PT item and routine samples, and an assigned value with too much uncertainty can score a lab unsatisfactory for reasons outside the lab. Document it with evidence: the item's condition, a re-measurement and the provider's data on its assigned value. Raise it with the provider. The investigation is still written down.

**What happens to a lab that fails proficiency testing repeatedly?**

Under CLIA, unsuccessful participation brings sanctions. For a first failure, CMS may direct training or technical assistance if the lab shows it has taken steps to correct the problem. Reinstatement needs two consecutive satisfactory events and, today, at least six months. A rule proposed on October 8, 2026 would remove the six-month wait. Under TNI, a field of accreditation can be suspended, then revoked.

**What do I do when a PT shipment never arrives?**

Record it. Under CLIA, a missed event scores 0 unless narrow exceptions apply, and when a score does not reflect your testing, you must verify accuracy another way and document that check. Ask the provider about alternative assessment, as CAP told international labs to do during its July 2026 shipping disruptions. Under TNI, a missed study counts as a failed study.

## Sources and references

1. 42 CFR Part 493 Subpart H, Participation in Proficiency Testing

   Electronic Code of Federal Regulations

2. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, clauses 7.7.2 and 7.10

   International Organization for Standardization

3. CLIA: Virtual Access, Gynecologic Cytology Proficiency Testing, Personnel Qualifications, and Other Changes, proposed rule CMS-3478-P (Oct 8, 2026)

Federal Register

**Brandon Holland**

**Marketing & Operations Digital Solutions Architect**

Brandon Holland is LabLynx's Marketing & Operations Digital Solutions Architect. He builds and runs the digital systems behind the company's public surface, from the website and content architecture to the tooling that keeps product information accurate everywhere it appears. He writes about laboratory informatics from the systems side: how lab records get structured, searched, and kept defensible as a lab scales.

**Read the current version online**

https://www.lablynx.com/resources/articles/proficiency-testing-failure-investigation/

Downloaded October 19, 2026. LabLynx builds laboratory informatics software: LIMS, ELN, LIS and lab automation.