PROFICIENCY TESTING (PT) AND EXTERNAL QUALITY ASSESSMENT (EQA)

Implementation Handout for Clinical Laboratory Professionals
Best practices aligned with ISO 15189:2022 and key CLIA '88 requirements

Purpose: This practical handout provides a structured approach to planning, implementing, monitoring, and improving a PT/EQA programme in clinical laboratories.

1. Key Concepts

External quality assessment (EQA) is an external evaluation of laboratory performance against predetermined criteria, commonly using interlaboratory comparison. Proficiency testing (PT) is a widely used form of such external assessment. ISO 15189:2022 uses the term EQA and requires participation in an appropriate EQA programme for examinations and interpretation, including point-of-care testing (POCT).

- PT/EQA complements internal quality control (IQC); it does not replace it.
- PT/EQA assesses external comparability, analytical performance and, in some circumstances, broader elements of the testing process.
- When a suitable EQA programme is unavailable, alternative approaches such as sample exchange or other interlaboratory comparisons should be considered.

2. Core ISO 15189:2022 Expectations

- Maintain a planned EQA/PT programme appropriate to the laboratory's scope.
- Select EQA activities appropriate to the examination method and interpretation of results.
- Include applicable POCT examination methods.
- Review and evaluate EQA performance, including trends and significant deviations.
- Investigate unacceptable or questionable performance and implement corrective action.
- Evaluate the effectiveness of corrective action and prevent recurrence.
- Use alternative interlaboratory comparisons when suitable EQA is not available. This includes inter-laboratory split samples, testing retained reference materials, or analyzing well-characterized clinical specimens.
- Retain evidence of participation, review, investigation, action and follow-up.

ISO 15189:2022 Shift Note: Modern compliance treats PT surveys as active clinical risk-assessment inputs. A passing grade with a negative trending bias demands operational intervention before an absolute analytical failure occurs

3. Key CLIA '88 PT Principles

For CLIA-regulated laboratories performing applicable nonwaived testing, participation in CMS-approved PT programmes is required. PT samples must be treated like patient specimens in the ordinary course of testing.

- Do not refer PT samples to another laboratory for analysis.
- Use the same instrument or method used for patient specimen testing, consistent with normal practice.
- Test PT samples the same way and the same number of times as patient specimens.
- Do not perform special repeats, special handling, or special consultation solely because the material is a PT sample.

Always verify the current Centers for Medicare and Medicaid Services (CMS)-approved PT programme list and the current list of nonwaived testing for which PT is required, because programme details and regulatory lists can change.

4. Build a PT/EQA Matrix

Examination	Method/Instrument	PT/EQA available?	Frequency	Provider/ILC	Responsible person	Status
Glucose	Chemistry analyser	Yes	Per scheme	Provider A	Chemistry lead	Active

Specialized assay	Specialized method	No	Defined alternative	Reference/peer lab	Section lead	Alternative EQA

5. Recommended Implementation Workflow

- **PLAN:** Define examinations, methods, sites, POCT activities, risks, available schemes and alternative EQA needs.
- **ENROL:** Choose appropriate providers; confirm regulatory approval where required.
- **RECEIVE:** Log samples, check condition and storage, and protect integrity and confidentiality.
- **TEST:** Process the material using normal personnel, procedures, instruments and workflow.
- **REPORT:** Submit results accurately by the provider deadline.
- **REVIEW:** Assess acceptability, bias, peer-group performance, trends and clinical significance.
- **ACT:** Investigate poor performance, correct the cause, assess patient impact and verify effectiveness.
- **IMPROVE:** Trend results and feed lessons into IQC, competency, risk management and management review.

6. How to Handle PT/EQA Samples

Good practice checklist:

- Receive and log the material.
- Check integrity, storage conditions and expiry/instructions.
- Test within the required timeframe.
- Use routine procedures and routine personnel.
- Use routine calibration and routine IQC processes.
- Use the same verification/release process applied to patient specimens.
- Submit the result by the required deadline.
- Do not share results or seek answers before submission.

7. Review Results—Do More Than 'Pass' or 'Fail'

Performance	Interpretation	Required response
Acceptable	Meets stated criteria	Document review and trend performance.
Questionable/Warning	Borderline or concerning pattern	Review method, IQC and trends; investigate as indicated.
Unacceptable	Does not meet stated criteria	Immediate investigation, corrective action and effectiveness review.

8. Investigating Unsatisfactory Performance

Consider the following categories during root-cause analysis:

- **Personnel**: training, competency, transcription or procedural error.
- **Equipment**: malfunction, maintenance, calibration or environmental instability.
- **Reagents/materials**: lot change, storage, expiry, preparation or matrix effects.
- **Method**: bias, interference, calculation or analytical range problems.
- **PT/EQA material**: stability, transport damage or commutability concerns.
- **Quality system**: inadequate SOPs, weak **IQC response, insufficient verification or risk controls.**

Useful tools include the 5 Whys, fishbone analysis, trend analysis and review of IQC, calibration, maintenance and recent patient results.

Root-Cause Analysis (RCA) Framework for Unsatisfactory Scores

Step 1: Clerical & Technical Pre-Screen — Investigate simple errors immediately. Verify transcription entries, instrument method codes, and reagent configurations. Audit sample matrix storage records, reconstitution volumes, and pipetting calibration dates.

Step 2: Analytical Performance Profiling — Evaluate daily internal Quality Control (QC) performance logs around the testing window. Examine LJ charts to look for shifting biases, sudden standard deviations, or subtle systematic drift trends.

Step 3: Clinical Risk and Safety Screening — Explicitly map potential clinical exposure. Evaluate if patient testing cohorts encountered systemic bias during the impacted timeline. Determine if critical reference boundaries or individual findings shifted.

Step 4: Operator and Training Review — Review training backgrounds for testing specialists involved. Audit compliance tracking against standard operating protocol baselines to find operational deviations.

9. Corrective Action Framework

1. CONTAIN – Control the immediate risk and assess whether patient results may have been affected.
2. INVESTIGATE – Identify the immediate and root causes using objective evidence.
3. CORRECT – Address the root cause—not merely the observed PT result.
4. VERIFY – Demonstrate effectiveness through subsequent data, EQA, IQC, comparisons or competency evidence.
5. LEARN – Prevent recurrence by improving procedures, training, controls or risk management.

10. PT/EQA and IQC: Complementary Tools

IQC	PT/EQA
Routine and frequent monitoring	Periodic external assessment
Detects day-to-day instability	Assesses comparability with external criteria or peers
Supports immediate run acceptance/rejection	Detects longer-term bias and systematic problems
Internal laboratory control system	Independent external/interlaboratory comparison

11. Trend and Management Review

- Overall acceptable performance rate.
- Repeated failures or recurrent warnings.
- Bias direction and magnitude over time.
- Method-, instrument-, site- or discipline-specific patterns.
- Time taken to complete investigations and corrective actions.
- Effectiveness and recurrence of corrective actions.
- Examinations without suitable EQA and alternative arrangements.
- Links between EQA findings, IQC, audits, complaints, risk and patient impact.

12. Common Mistakes to Avoid

- Treating PT/EQA as a compliance exercise only.
- Giving PT samples special handling.
- Repeating PT samples until a desired result is obtained when this is not normal patient practice.
- Improper referral of PT samples.
- Closing investigations without establishing root cause.
- Failing to assess potential impact on patient results.
- Implementing action without checking effectiveness.
- Ignoring trends or recurring borderline performance.
- Failing to document alternative EQA when formal PT is unavailable.

13. Documentation Checklist

- PT/EQA scope and matrix

- Provider selection and approval evidence where applicable
- Enrollment and schedule records
- Sample receipt and testing records
- Submitted results and provider reports
- Result review and trend analysis
- Investigations and root-cause analysis
- Corrective actions and effectiveness checks
- Alternative EQA/ILC records
- Management review records

14. Roles and Responsibilities

Laboratory Director/Head: Provide oversight, resources and review of significant quality issues.
Quality Manager: Coordinate the programme, monitor documentation, trends and corrective action.
Section Supervisor: Ensure correct processing, review and investigation within the technical area.
Testing Personnel: Handle material as required, follow routine procedures and report accurately.

15. Quick-Reference Checklist

- Is every applicable examination covered by an appropriate PT/EQA or alternative external comparison?
- Are PT samples handled like patient specimens?
- Are routine staff, methods and instruments used?
- Are results reviewed beyond a simple pass/fail decision?
- Are unacceptable and concerning results investigated?
- Is patient impact assessed where relevant?
- Are corrective actions based on root cause?
- Is effectiveness demonstrated and documented?
- Are PT/EQA results trended and reviewed by management?

Key Messages

- "PT/EQA is an independent quality improvement tool—not merely a score."
- "An unacceptable result should trigger learning, investigation and effective improvement."
- "PT/EQA should be integrated with IQC, competency, risk management and patient-result review."
- "For CLIA, current CMS requirements and approved programme lists should be checked for the laboratory's actual testing scope."

Selected References

1. ISO 15189:2022, Medical laboratories — Requirements for quality and competence.
2. ILAC-P9:01/2024, Policy for Proficiency Testing and/or Interlaboratory Comparisons other than Proficiency Testing.
3. CMS, Proficiency Testing Program Requirements: General & Cytology (current CMS guidance).
4. CMS, Proficiency Testing Programs—current approved programmes and applicable nonwaived testing list.
5. 42 CFR Part 493 (CLIA regulations).

Educational note: This handout is an implementation aid and does not replace applicable laws, regulations, accreditation requirements, provider instructions or the licensed text of ISO 15189:2022.