MEDLAB BASICS · STUDY SHEET

Quality Control, Validation and Regulation

Levey-Jennings charts and Westgard rules, sigma, method verification, calibration, reference intervals, proficiency testing, competency, CLIA, POCT, error phases and reporting

22 sources + more detail
medlabbasics.com/sheets/lab-qc-quality.html
checked Nov 2026

1 QC statistics

MEASURE	FORMULA	WHAT IT TELLS YOU
Mean	Sum of the control results ÷ number of results	Center of the control's distribution; the laboratory's own target
Standard deviation (SD)	$\sqrt{[\Sigma(x - \text{mean})^2 \div (n - 1)]}$	Spread of results: imprecision (random error), in the analyte's units
Coefficient of variation (CV)	SD ÷ mean × 100	Imprecision as a percent, so methods and levels can be compared
Bias	(Laboratory mean – target or peer mean) ÷ target × 100	Inaccuracy (systematic error)
z-score (SD index)	(Result – mean) ÷ SD	How many SDs a result lies from the mean; what the Westgard rules read
Total error (TE)	|Bias| + 1.96 × CV	Worst likely error of a single result: bias plus about 2 SD of imprecision
Sigma metric	(TEa – |bias|) ÷ CV, all in %	6 or more is world class; below 3 is poor and needs strict QC

TERM	MEANING	ERROR IT REFLECTS
Accuracy	Closeness of results to the true value	Systematic error (bias); can be found and corrected, for example by calibration
Precision	Closeness of repeated results to each other	Random error; can be reduced but not removed
Shift	Control results jump to a new level and stay there	Systematic: new reagent or control lot, calibration
Trend (drift)	Results move steadily up or down over several runs	Systematic: progressive change such as reagent deterioration

EXAM TIP Worked: control results 98, 100, 102, 99 and 101 mg/dL. Mean = 500 ÷ 5 = 100. Deviations −2, 0, +2, −1, +1; squares sum to 10; 10 ÷ 4 = 2.5; SD = √2.5 = 1.58 mg/dL. CV = 1.58 ÷ 100 × 100 = 1.6%. A result of 104 gives z = (104 − 100) ÷ 1.58 = +2.5.

2 Westgard multirules

Applied as in the Westgard Rules Check calculator: every rejection rule checked on every run, 1-2s reported as a warning only when nothing else fires. The calculator checks 4-1s within one level and does not check 10x; Westgard allows 4-1s and 10x to count across levels.

RULE	VIOLATED WHEN	ERROR TYPE	ACTION
1-2s	One result beyond ±2 SD	Warning only	Inspect with the other rules; do not reject on 1-2s alone
1-3s	One result beyond ±3 SD	Random (or the start of a large systematic error)	Reject the run
2-2s	Two results beyond the same 2 SD limit (both above +2 or both below −2): the same level in two consecutive runs, or both levels in one run	Systematic	Reject the run
R-4s	Within one run, one level beyond +2 SD and the other beyond −2 SD. Never across runs	Random	Reject the run
4-1s	Four consecutive results beyond the same 1 SD limit (all above +1 or all below −1)	Systematic	Reject the run
10x	Ten consecutive results on the same side of the mean	Systematic	Reject the run

- Use the laboratory's own mean and SD for each control lot, not the manufacturer's printed range.
- 1-3s and R-4s point to random error: for example clots or debris in the pipette, inadequate cleaning, electronic noise or an operator error.
- 2-2s, 4-1s and 10x point to systematic error: calibration, a new reagent or control lot, deteriorating reagent, wrong fluid levels or temperature.
- After a rejection: stop reporting, test a fresh vial of control (rules out a spoiled vial), find and fix the cause, rerun controls, then review every patient result since the last acceptable run.

SAFETY Repeating the same control until it falls inside the limits is not troubleshooting. CLIA requires the laboratory to evaluate all patient results from the failed run and since the last acceptable run (42 CFR 493.1282).

3 Validation, calibration and reference intervals

SITUATION	WHAT CLIA REQUIRES BEFORE PATIENT RESULTS	NOTES
Unmodified FDA-cleared or approved nonwaived test (verification)	Accuracy, precision, reportable range; verify the manufacturer's reference interval fits the patient population	Each instrument, even the same make and model
Modified FDA test, laboratory-developed test, or no manufacturer specifications (establishment)	Accuracy, precision, analytical sensitivity, analytical specificity including interfering substances, reportable range, reference intervals	42 CFR 493.1253(b)(2)
Calibration verification	Follow the manufacturer's instructions, or the laboratory's own criteria using at least 3 levels (minimal or zero, mid-point, near the upper limit of the reportable range); at least every 6 months and after a trigger	Triggers: complete reagent change (unless the lot change is shown not to matter), major maintenance or critical part replaced, QC shift or trend that other fixes do not correct, or the laboratory's own schedule
Reference interval establishment	At least 120 reference subjects per group (CLSI C28-A3)	Central 95% of healthy subjects
Reference interval transference	Test 20 local healthy subjects: accept if no more than 2 fall outside	If 3 or more fall outside, test 20 more; if 3 or more fail again, re-examine the method and population

EXAM TIP Method comparison: run at least 40 patient specimens across the range on both methods. With regression y = a + bx, systematic error at decision level Xc is (a + b·Xc) − Xc. The y-intercept points to constant error and a slope away from 1.00 to proportional error. r tells you whether the range was wide enough (0.99 or more), not whether the method is acceptable.

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4 Proficiency testing and competency

TOPIC	RULE (42 CFR 493)
Handling PT samples	Test with the routine workload, by the staff who usually do the test, by the routine method, the same number of times as patient specimens
Forbidden	Discussing PT results with another laboratory before the deadline; sending PT samples (or any part) to another laboratory for a test you perform. Intentional referral can cost the certificate for at least a year
Passing score	At least 80% for most analytes and events; 100% for ABO group and D typing, unexpected antibody detection and compatibility testing
Unsatisfactory	Below the passing score in one event; not participating or returning late scores 0
Unsuccessful	Unsatisfactory for the same analyte in 2 consecutive events or 2 of 3 consecutive events: triggers CMS action
No PT available (alternative assessment)	Verify accuracy at least twice a year (split samples, blind specimens, other means)
Competency, nonwaived testing	Six elements for every test: (1) direct observation of routine testing, (2) monitoring recording and reporting of results, (3) review of worksheets, QC, PT and maintenance records, (4) direct observation of instrument maintenance and function checks, (5) testing previously analyzed, blind or PT samples, (6) problem-solving
Competency timing	Twice in the first year of testing, then once a year; retrain and assess before reporting on a new method or instrument

EXAM TIP Training, PT results and annual performance appraisals do not, on their own, meet the competency requirement. Waived-only testing needs trained staff who follow the package insert, but CLIA does not require competency assessment for it.

5 CLIA, accreditation and POCT

CATEGORY	HOW A TEST GETS THERE	MAIN REQUIREMENTS
Waived	Cleared for home use, or so simple and accurate that error is negligible, or no reasonable risk of harm if done wrong (examples: dipstick urinalysis, urine hCG by visual color, fecal occult blood, home-use glucose meters, spun microhematocrit)	Certificate of waiver; follow the manufacturer's instructions exactly
Moderate complexity (includes PPM)	FDA scores 7 criteria from 1 to 3; total 12 or less	QC, PT, verification, competency; testing personnel need at least a high school diploma with documented training
High complexity	Total score above 12; any test not yet categorized	All of the above, stricter personnel rules (for example an associate degree in laboratory science or equivalent)

- Agencies: FDA categorizes tests; CMS runs CLIA and certifies laboratories; CDC provides technical support, studies and the advisory committee.
- Certificates: waiver, PPM, registration, compliance (state inspection) and accreditation (deemed status through a CMS-approved organization: CAP, The Joint Commission, COLA, AABB, A2LA, ACHC, ASHI).
- Default QC for quantitative nonwaived tests is two levels each day of testing; qualitative tests need a positive and a negative control. IQCP is the voluntary risk-based alternative.
- IQCP = risk assessment (specimen, test system, reagent, environment, testing personnel) + quality control plan + quality assessment. Every specialty except pathology is eligible.
- POCT oversight: a POCT coordinator and director, operator records with certification dates, devices that lock out when QC is overdue or fails, connectivity to the LIS, and the same CLIA rules as any test of that complexity.

6 Errors, reporting and turnaround time

PHASE	EXAMPLES	CONTROLS
Preanalytical (most errors)	Wrong patient or mislabeled tube, wrong tube or additive, hemolysis, prolonged tourniquet or fist clenching (false high potassium), delayed transport, IV contamination	Positive patient identification, specimen rejection criteria, written collection procedures, delta checks
Analytical	Failed QC, expired reagent, calibration error, result above the reportable range reported without dilution, interference	QC and Westgard rules, calibration verification, maintenance, dilution protocols
Postanalytical	Transcription error, result sent to the wrong chart, critical value not called, delayed report	Interfaces and autoverification, critical value policy, corrected reports

- Critical (panic) value: the laboratory must alert the person who ordered the test, or who uses the result, immediately. Laboratory policy usually adds read-back and a record of who was told and when.
- Corrected report: promptly tell the ordering provider of the error, send a corrected report, and keep both the original and the corrected report.
- Delta check: compares a result with the same patient's previous result; a change too large for biology suggests misidentification or another error.
- Autoverification: rules in the LIS or middleware release results without manual review when they pass QC, flags, limit and delta checks (CLSI AUTO-10A and AUTO-15).
- Turnaround time is right-skewed: report the median and the time by which 90% of tests are done, not the mean alone. Most delays are pre- or postanalytical.
- Records: QC, PT, patient test records and reports at least 2 years; immunohematology and transfusion records follow the FDA blood rules in 21 CFR 606.160.

7 Management and education (MLS only)

BLOOM'S LEVEL (REVISED)	LEARNER CAN	OBJECTIVE VERBS
1 Remember	Recall facts	List, name, define
2 Understand	Explain, classify, compare	Explain, describe, compare
3 Apply	Use knowledge in a new situation	Calculate, perform, use
4 Analyze	Break information into parts	Differentiate, troubleshoot, interpret
5 Evaluate	Judge value or quality	Judge, appraise, decide
6 Create	Produce something new	Design, develop, write

- Write objectives in behavioral terms: what the learner will be able to do, with a measurable verb ('calculate the CV', not 'understand QC').
- Domains: cognitive (knowledge), psychomotor (bench skills, such as making a smear), affective (attitudes, such as professionalism).
- Staffing: enough staff to cover the workload, a current competency-based job description for each position, orientation, training, competency assessment, continuing education and an annual performance appraisal.
- Budget: part of every plan, with staff, training, equipment, reagents, supplies and QC material; supply quantification each year feeds the budget.
- Quality management: the 12 quality system essentials and the plan-do-check-act cycle (see In depth).

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