

From Hire to Sign-Out: Competency Is a Record, Not a Course

Your new analyst's training is signed off and she's doing fine. In February the assessor asks for the assessment due six months after her first patient specimen, and the day she first reported alone.

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October 9, 2026 · 8 min read

IN BRIEF

What is laboratory competency assessment? Competency assessment is a documented record that a person was observed, checked and authorized for a specific test. CLIA requires six elements, twice in the first year a person tests patient specimens, then yearly. ISO/IEC 17025 requires written authorization and monitoring, at intervals the lab sets.

Key takeaways

- Sign-out on a method is the day the director's written list stops requiring review of a person's results.
- CLIA's first year starts with the first patient specimen a person tests, which can be weeks or months after hire.
- CAP has allowed virtual direct observation since November 3, 2025, with every in-person rule still applying.
- Time to sign-out takes two dates per method beyond the hire date, and no published benchmark exists for it.
- Authorization by method and instrument, with dates, answers the assessor's question from one record.

Your newest analyst started in March and tested her first patient specimens in May. She keeps up on the bench, and when you ask how she's doing, the answer is "fine." In November you signed off her training on her third method.

In February the assessor opens her file and asks two questions. Where is her first semiannual assessment, due by November, six months after her first patient specimen? And on what date was she first allowed to report a result alone on each method? Her training record answers neither one.

Competency is a dated record with six elements, and its clock starts at her first patient specimen. The time from hire to her first result reported alone is a number you can measure and shorten, whether your records live in a binder or a [laboratory information management system](#). The same applies in CLIA, CAP and ISO/IEC 17025 labs, and the table below shows where they differ.

What does a competency record actually have to contain?

A competency record shows all six CLIA elements for each person who tests, with the assessor's sign-off. You know the six already from [42 CFR 493.1451](#). Two things trip labs up: when each assessment is due and how many they need.

CLIA's first year starts with her first patient specimen, and that can come weeks or months after her hire date. Under [CAP accreditation](#), you need all six elements on each test system, so one test run on two systems needs two assessments.

Her sign-out date is already in a record you keep. [CLIA rules for laboratories](#) require the director's written list of the tests each person may perform and whether results need review before reporting. CLIA never uses the word sign-out, but in practice her sign-out date on a method is the day her results on that method no longer need review.

An ISO/IEC 17025 lab keeps the same two records under clause 6.2.

	CLIA	CAP	ISO/IEC 17025
Six elements	Every person who tests (493.1451)	All six on each test system (GEN.55500)	Monitoring of competence (6.2.5)
Timing	Twice in year one of patient testing, then yearly	By month 7 and 12, then yearly (GEN.55505)	Intervals the lab sets, infrequent tests included
Who assesses	Technical supervisor or consultant, or a delegate named in writing	A qualified assessor (GEN.55510)	The lab decides and records it
Authorization record	The director's written list, kept current	Same as CLIA in US labs	Authorization to report, review and authorize results (6.2.6)

ISO 15189:2022 covers medical lab personnel in clause 6.2, with requirements for competence, continuing education and records.

What changed in 2025 and 2026?

Direct observation can now happen over live video. A proposed CLIA rule would also change director visits and remote review, but CMS says it does not change competency assessment.

Video matters most if she works a shift you're never on, because direct observation is the element that slips. The regulation never required observation in person. CMS's guidance did, and CMS withdrew it. [CAP's update on virtual observation](#) followed, and every in-person rule still applies. The observer is qualified for the complexity of testing and delegated by name or job title. The session is live with real-time audio, every step is visible, and recorded video doesn't count.

The [proposed rule, CMS-3478-P](#) isn't final. On competency, CMS is plain: "No individual is permitted to perform testing without first completing the required training and demonstrating competency."

COMPETENCY ASSESSMENT: WHAT MOVED, AND WHEN

Jun 23, 2025

CMS removes its guidance that direct observation be performed in person.

Nov 3, 2025

CAP allows virtual direct observation where law permits, with every in-person provision still applying.

Oct 8, 2026

CMS publishes proposed rule CMS-3478-P on director qualifications, on-site visits and virtual access.

Dec 7, 2026

Comments on the proposed rule close. CMS has proposed no effective date.

How long does it take a new analyst to sign out alone, and why does nobody know?

Nobody knows, because no one has published a benchmark for it in clinical or 17025 labs. The one published range, from a 2024 report on immunohematology training, is two weeks to four months, depending on the job's complexity.

So measure your own. You already have her hire date. Add two more for each method: the day she first tested a patient specimen, which starts CLIA's first year, and the day she first reported a result without review. In a 17025 lab, use her first run on real samples and the date she was authorized to report. The gap from hire to that last date is your time to sign-out.

Her hire date is in the HR file. Her first patient specimen is in her training record, or under her user ID in your LIS. Her sign-out date belongs on the director's written authorization. If review stopped informally, use her first result released without a co-sign.

If her first patient specimen was May 12, her first assessment is due by November 12 (December 12 under CAP's GEN.55505), and her second by May 12 the next year.

If you measure one thing about onboarding, measure time to sign-out. That number tells you what being short-staffed costs you on the bench. One respondent to MLO's 2026 survey wrote, "I cannot take time away from the lab to attend."

NOTE

A shorter time to sign-out only counts if the record stays complete. One ASCP Community member put the risk plainly: "If we shorten the training time to two days in each department, then we risk lack of competency." Cut the waiting time between steps, but don't skip any of them.

What shortens it without cutting corners?

Four habits shorten it without skipping an element. Nobody has measured what each saves.

Authorize by method, so she signs out on one method while the others stay under review. Sign out each method when its evidence is complete, about day 30 at the earliest for a simple method and later for a high-complexity one.

Run the blind sample in week two from saved specimens instead of in month five. It comes before patient testing, so it counts as training. After her first patient specimen, your delegated assessor's observations and blind samples can count toward the first semiannual assessment if your written policy allows it.

Schedule the observation, on video where your accreditor allows it, and build the problem-solving case from a real nonconformance.

- Day 1: Record her start date, her methods and a training plan for each, with a named, qualified trainer.
Authorization: “review required before any report.”
- Weeks 1 to 2: SOP review and observed performance on method 1.
- Week 2: Blind or previously analyzed samples on method 1, as training records.
- Weeks 2 to 3: Observed instrument maintenance and function checks.
- Weeks 3 to 4: Supervised patient runs, every result reviewed. Record her first patient specimen date.
- After that date: The delegated assessor’s observation and blind sample, toward the first semiannual assessment.
- Day 30 at the earliest: Sign out method 1 once its evidence is complete, and date the authorization.
- Days 30 to 60: Repeat for methods 2 and 3. Monitor reporting on signed-out methods.
- Days 60 to 90: The problem-solving case, from a nonconformance or PT failure.
- Day 90: Count days from hire to sign-out per method. Date both first-year assessments from her first specimen.

What do assessors cite, and what does the record look like when it works?

In February the assessor is looking for missing records, and CAP has said which ones. GEN.55500 was first on CAP’s top ten deficiency list for 2022 and fifth on its 2025 list. CAP cites it most often when labs don’t document all six elements, can’t produce the supporting records, or lump all their manual tests into one test system.

CMS statements of deficiency tell the same story. One lab had no first-year semiannual assessment for its one new testing person. Another had two assessments a year apart with nothing between them. A third had forms missing the six elements for every testing person.

A record that holds up has one row for each person and each method. If the steps change from one instrument to another, the row names the instrument. Each row shows the six elements and how each was

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assessed, with the supporting worksheet or log. It names the date and an assessor who was qualified and delegated in writing.

The row also carries the date she was authorized to report alone and the date her next assessment is due. It can live on paper or in a [laboratory management system](#).

When every date for her sits on one row, the February question takes a minute to answer.

How a LIMS helps with competency records

A LIMS doesn't assess anyone. Your technical supervisor still observes, reviews and signs. A LIMS already records who reported each result and when, so it's the natural place to record who was authorized to report them.

How LabLynx handles this

When we bring a lab onto LabLynx LIMS, we set up each analyst's personnel record to answer the assessor's question. We build each person's authorizations from the director's written list, method by method, and load the competency history you already have. Each authorization is held by method and by instrument, with the date it was granted, so "Who was allowed to report this result on that day?" becomes one query instead of a binder search.

Each competency assessment sits on the person's record with its date, and the next due date shows on the same record. You can start before any of that. For your newest analyst, write down the date they first tested a patient specimen and the date of their first result reported alone, by method.

Frequently asked questions

What are the six elements of competency assessment under CLIA?

42 CFR 493.1451(b)(8) names six. The assessor directly observes routine patient testing, monitors how results are recorded and reported, and reviews worksheets, QC, proficiency testing and maintenance records. The assessor also observes instrument maintenance and function checks. The person tests previously analyzed, blind or proficiency samples, and the assessor checks problem-solving skills.

How often must competency be assessed?

Under CLIA, at least semiannually during the first year the person tests patient specimens, then at least annually, and again before reporting patient results after a method or instrument change. CAP's GEN.55505 puts the first assessment within seven months of starting testing and the second by twelve. ISO/IEC 17025 sets no interval, so the laboratory defines one and keeps the records.

Can competency assessment be done remotely?

Direct observation can be virtual. CMS removed its in-person guidance on June 23, 2025, and CAP allowed virtual direct observation on November 3, 2025, where law permits. Every in-person rule still applies. The observer is qualified and delegated, the session is live with real-time audio, every step is visible, recorded video does not count, and the observer's sign-off is kept.

Does ISO/IEC 17025 require competency records?

Yes. Clause 6.2 calls for documented competence requirements for each role, and for procedures and records covering how those requirements are set, selection, training, supervision, authorization and the monitoring of competence. People are authorized for specific activities, including reporting, reviewing and authorizing results. Accreditation bodies expect those records at assessment. The standard sets no interval, so the laboratory defines one.

How long does it take a new lab analyst to work independently?

No published benchmark exists. The only range in print, from a 2024 session report on immunohematology, is two weeks to four months, depending on the complexity of the position. Measure your own by recording the date of each person's first patient specimen on a method and the date of their first result reported alone. A written plan and an early blind sample help shorten it.

Who can perform competency assessments?

Under CLIA, the technical supervisor for high complexity testing or the technical consultant for moderate complexity testing. Either may delegate in writing to a person who meets the same qualifications, and the technical supervisor stays responsible for the evaluations and the documentation. CAP sets assessor qualifications in GEN.55510. Under ISO/IEC 17025, the laboratory decides who assesses and records that decision.

Sources and references

1. [42 CFR 493.1451 Standard: Technical supervisor responsibilities](#)

Electronic Code of Federal Regulations

2. [ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, clause 6.2](#)

International Organization for Standardization

3. [2024 Checklist Edition Update, November 3, 2025 \(virtual direct observation\)](#)

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