



EDUCATIONAL RESOURCES

Top Laboratory Deficiencies of 2020-2021

Common inspection citations:
Learn what they are and how to avoid them



CLINICAL LABORATORY



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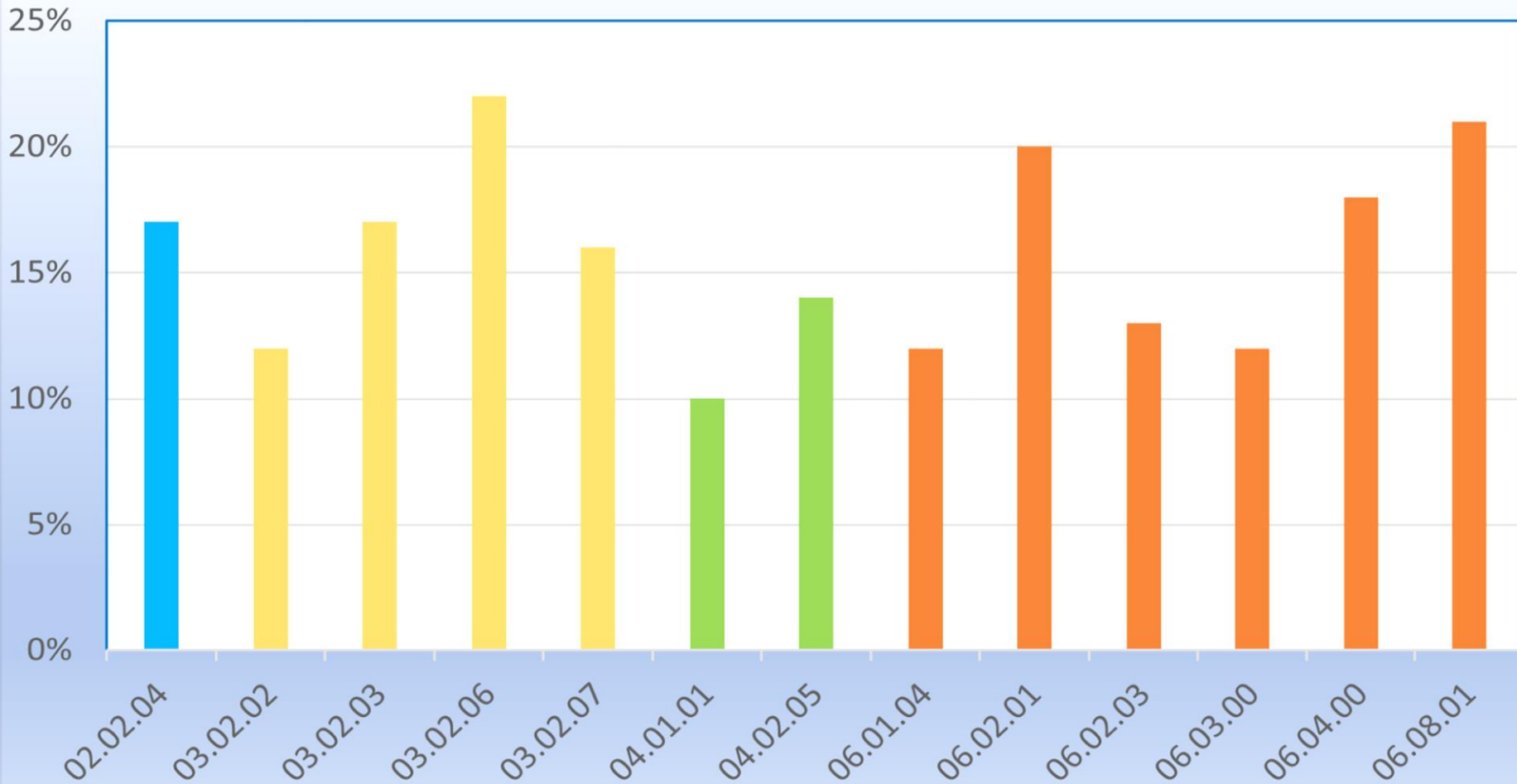
Welcome

- So glad you are here .
- Laboratories are among the most highly regulated areas in healthcare.
- Data presented reflects deficiencies cited on surveys in 2020 and 2021.
- As your partner in achieving quality and accuracy in laboratory services, ACHC's intent is to educate and help close gaps in compliance.
- Let's do this workshop!

Objectives

- Upon completion of the presentation, participants will be able to:
 - Identify the most frequently cited laboratory standards in 2020-2021.
 - Understand these standards to analyze their own laboratory's practices.
 - Describe tips to comply with these challenging standards.
 - Implement methods to prevent deficiencies.

Top Laboratory Deficiencies



Personnel

Waived Testing

Proficiency Tests

Analytic Systems

Personnel Citations



Standard 02.02.04

Testing Personnel Competency/Evaluation

Overview:

Technical supervisor/consultant is responsible for evaluating/documenting staff competency to perform tests and report results.

Required elements:

1. Direct observations of routine test performance, including patient preparation (if applicable), specimen handling, processing, and testing.
2. Monitoring the recording and reporting of test results.
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
4. Direct observation of instrument maintenance and function checks.
5. Assessing test performance through testing previously analyzed specimens, internal blind samples or external proficiency testing samples.
6. Assessing problem-solving skills.

Required intervals:

- **Semiannually during the first year** the individual tests patient specimens.
- **Thereafter, annually** unless methodology/instrumentation changes, in which case, reevaluate prior to reporting patient test results.

§493.1451(b)(8)(i-vi),(9)

§493.1413(b)(8)(i-iv),(9)

Standard 02.02.04

Testing Personnel Competency/Evaluation

Frequency: 17%

Comment: This standard was cited when required elements of the evaluation were not documented as completed or when evaluations were not performed within required time frames.

Examples of Surveyor findings:

- Competency evaluation was not completed annually for all personnel.
- Technical staff did not have all 6 required elements evaluated for each test system in the laboratory.
- Education credentials were not available for review at time of survey

Standard 02.02.04

Testing Personnel Competency/Evaluation

Tips for compliance:

- Don't confuse training documentation with competency assessment.
- Cover the 6 elements for all non-waived tests/test systems (including point of care) for all who perform/report patient results.
- An easy way to document problem-solving is by quiz.
- Create a tracking document that lists each test/test system and meet the frequency requirements:
 - Semi-annual in 1st year of employment (usually 6 months & 1 year).
 - Annually thereafter unless new method/instrument - then prior to reporting
- Make sure competency is assessed by a qualified supervisor:
 - *Semi-annual*: Lab Medical Director or Technical Supervisor (Blood Bank requires MD/DO/DPM & 1 year training/experience; Cytology & Pathology requires MD/DO & board certification; most other clinical specialties minimally require BS & 4 years training/experience). Note: Technical Consultant of Moderate Complexity Lab: minimum requirement is BS & 2 years training/experience.
 - *Annual*: General Supervisor, if delegated. (Requires BS & 1 yr. training/experience; AD & 2 yrs. training/experience). Note: The General Supervisor position is not applicable to Moderate Complexity Labs.
- Assess competencies based on CLIA-position responsibilities for Technical Supervisors/Consultants, Clinical Consultants, and General Supervisors at a frequency determined by the lab. Remember, if these individuals also perform/report tests, they must also do the 6 elements required for testing personnel.

Waived Testing Citations



Standard 03.02.02

Waived Lab Supervisor Responsibilities

Overview:

- The laboratory supervisor oversees operation and administration including:
 - Oversight of personnel competency.
 - Implementation of procedures with written policies.
 - Providing for appropriate QC and quality assurance monitoring.
 - Ensuring policies/procedures are followed.

Standard 03.02.02

Waived Lab Supervisor Responsibilities

Frequency: 12%

Comment: This standard was typically cited when quality control measures were not implemented and documented or when manufacturer's instructions were not followed.

Examples of Surveyor Findings:

- Thermometer and hygrometer had not been checked or calibrated.
- Refrigerator used for specimen and control storage was not being monitored.
- Log sheets were not filled out when quality control was tested.
- The calibration for the timer in use was expired.
- Laboratory Director had not signed off on procedures.
- Comparison studies are not being performed between the clinic and main lab as per policy for urine dipstick tests. (Note: You must follow your policy when stricter than a standard).

Standard 03.02.02

Waived Lab Supervisor Responsibilities

Tips for Compliance:

- Know what testing is being done and where within your organization.
- Ensure that the supervisor assigned to oversee waived testing is familiar with the ACHC standards related to waived testing.
- Ensure that for each waived test in use there is a current copy of manufacturer instructions.
- Create a comprehensive quality assurance plan to regularly monitor quality control and patient testing to ensure manufacturer instructions are followed.

Standard 03.02.03

Waived Testing Personnel Competency

Overview:

The laboratory supervisor is responsible for initial training and for evaluating the competency of all testing personnel.

The laboratory supervisor ensures that competency for testing personnel is evaluated at least annually.

Note: If more stringent state or local regulations are in place for competency assessment of waived testing, they must be followed.

Standard 03.02.03

Waived Testing Personnel Competency

Frequency: 17%

Comment: The standard was cited when personnel records did not have documentation of initial training and annual competency evaluations.

Examples of Surveyor Findings:

- No documentation of training for laboratory testing.
- No documentation for initial orientation/training as well as annual competency assessment.
- No documented orientation, training, or competency for the use of the i-stat for testing of creatinine for CT patients.
- Training documents had not been reviewed by the laboratory supervisor.

Standard 03.02.03

Waived Testing Personnel Competency

Tips for compliance:

- Assign responsibility to the waived lab supervisor to:
 - ensure orientation and training is done and documented for all testing personnel.
 - evaluate competency of testing personnel at least annually.
- The director may determine the method(s) used to evaluate competency. Specify the method in a policy. You may use a quiz or a method you are already doing. Examples include, but are not limited to:
 - Review of Quality Control records, PM records, or Proficiency Testing results.
 - Monitor recording and reporting of patient test results.
- Be sure your policy matches your practice for method and frequency.
- Document the competency for each test for each testing personnel!

Standards 03.02.06/03.02.07

Manufacturer Instructions/Quality Control- Waived Testing

Overview:

The laboratory must maintain a current copy of the manufacturer's instructions for the tests performed and must follow the current stated manufacturer's instructions for:

- Specimens
- Reagents
- Storage and handling
- Safety precautions
- Quality control (performance, review before reporting patients, take corrective action as needed)
- Timing and temperature requirements
- Procedural steps
- Function checks, instrument maintenance and calibration if required
- Result interpretation and reporting

§493.15(e)(1)

Standard 03.02.06/03.02.07

Manufacturer Instructions/Quality Control-Waived Testing

Frequency: 03.02.06 at 22%/03.02.07 at 16%

Comment: These standards were cited when procedures and/or manufacturer's instructions were not available or not followed, when appropriate expiration dates were not recorded, or when quality control or required environmental readings were not performed/documentated.

Examples of Surveyor Findings:

- The laboratory lacked procedures and/or package inserts for the staff performing testing.
- Documentation showed that glucose meter control solutions and test strips were not dated when opened nor was the new expiration date noted on the solutions and strips.
- Temperature and humidity readings were not recorded to assure reagents were stored under the proper conditions as indicated by the manufacturer.
- Logs revealed the laboratory was not following Urine HCG manufacturer instruction for external positive/negative quality controls or internal controls for test performed.
- Documentation showed that quality controls were not conducted per manufacturer-indicated schedules or according to laboratory procedures.

Standards 03.02.06/03.02.07

Manufacturer Instructions/Quality Control- Waived Testing

Tips for compliance:

- Ensure there is a written detailed procedure or that the manufacturer's package insert is available for each test. If needed, obtain a copy of the instructions on the manufacturer's website.
- Follow manufacturer's instructions without modification.
- Ensure quality controls, internal and external, are tested at the manufacturer-required frequency.
 - The same staff who test patients must test QC.
 - Document Internal Controls at least once/day of testing for each device. Exception: instrument automatically locks & stops testing if QC is out.
 - Run and document External Controls at frequency specified in package insert. Usually, each new shipment, each new lot, each new operator.
 - Document corrective actions if QC is unacceptable.
 - The supervisor should review QC at least monthly for compliance. Follow your policy.
- Document daily temperatures of refrigerators and/or room temperature or humidity if the package insert specifies ranges for storage or testing.
- Document the lot number and expiration date of test kits.
- If instrumentation is used, perform all maintenance and calibrations as specified by the manufacturer.

Proficiency Testing Citations



Standard 04.01.01

Test Not Included in PT

Overview:

For those non-regulated tests (tests not included in subpart I of CLIA regulations) or tests for which compatible proficiency samples are not available from a CMS-approved proficiency program, the laboratory must verify the accuracy of the test or procedure twice annually.

§493.801(a)(2)(ii), §493.1236(c), (c)(1), (c)(2)

Standard 04.01.01

Test Not Included in PT

Frequency: 2020 at 2%; Increase seen in 2021 to 17%

Comment: This standard was cited when a non-regulated analyte was not enrolled in PT and the analyte's accuracy was not otherwise verified twice annually.

Examples of Surveyor Findings:

- No proficiency testing was being done for Gastric Occult Blood/Gastric pH and the laboratory did not have an alternate method to verify accuracy twice annually in place.
- The laboratory did not verify the accuracy of the Mohs test it performs at least twice per year as required since PT samples are not offered by a CMS-approved PT program.
- The laboratory did not enroll in PT for Ammonia or Transferrin. No alternate assessment of accuracy was performed.

Standard 04.01.01

Test Not Included in PT

Tips for compliance:

- Maintain a list of all tests performed with PT provider indicated.
- Enroll non-regulated analytes in an approved PT program whenever one is available.
- Create a tracking document that lists any tests not enrolled in a PT program.
- Establish a procedure detailing the method and acceptance criteria used to verify accuracy:
 - Blind testing of materials with known values.
 - Alternate external assessment program.
 - Split samples with another instrument or method.
 - Comparison with pictograph/slides from a reference source.
- Document the accuracy verification of tests not enrolled in PT at least twice annually.

Standard 04.02.05

Unsuccessful Performance by Analyte

Overview:

For a specific analyte or test, if two or more consecutive proficiency testing (PT) events are unsatisfactory, the analyte/test is deemed unsuccessful.

§493.837(f), §493.841(f), §493.843(f), §493.845(f), §493.851(f), §493.859(f), §493.865(e)

Standard 04.02.05

Unsuccessful Performance by Analyte

Frequency: 14%

Comment: This standard was cited when analytes had consecutive testing events with unsuccessful performance.

Examples of Surveyor Findings:

Unsuccessful performances were cited for the following analytes:

- Total Protein (BF): 2020-1 67%, 2020-2 67%
- D-Dimer: 2020-1 50%, 2020-0%
- CSF/BF Microscopy: 2020-1 67%, 2020-2 67%
- TSH: 2019-2 40%, 2020-1 40%

Standard 04.02.05

Unsuccessful Performance by Analyte

Tips for compliance:

- Ensure that test results are submitted by due dates.
- Conduct a complete investigation of all proficiency testing results that are less than 100%. Initial issues may be first evident with a score of 80%.
- Do not use “unexplained” or “random error” as a reason for the failure. Investigate the cause. Initial failures become repeat failures if only cursory initial investigations are completed.

Analytic Systems Citations



Standard 06.01.04

Procedure Approval

Overview:

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

§493.1251(d)

Standard 06.01.04

Procedure Approval

Frequency: 12%

Comment: Deficiencies were cited when the Laboratory Director did not approve procedures or changes in procedures before use.

Examples of Surveyor Findings:

- Most laboratory procedures were not approved by the current Medical Director.
- Most of the policies were not approved before being put into use.
- There was no evidence that the Laboratory Director reviewed and approved procedures when revised.

Standard 06.01.04

Procedure Approval

Tips for compliance:

- The director's responsibility to review and approve new and changed/revised policies and procedures cannot be delegated.
- The approval must be dated and occur prior to implementation.
- Approval documentation can be on paper or electronic.
- If there is a change in directors, the new director must review and approve all procedures.
- Annual review is not required, but periodic review is best practice. A coversheet in the manual may be used for a periodic review.

Standard 06.02.01

Essential Conditions

Overview:

Laboratories must define conditions for proper storage of reagents/specimens, test system operations, and results reporting. The conditions must be consistent with manufacturer's instructions and be monitored and documented if applicable:

- Water quality
- Temperature
- Humidity
- Protection from electrical fluctuations and interruptions in electrical current.

§493.1252(b)(1-4), §493.1282(b)(3)

Standard 06.02.01

Essential Conditions

Frequency: 20%

Comment: Deficiencies were cited when instruments were not certified or monitored, documentation was not maintained as per policy, and corrective action was not taken when necessary.

Examples of Surveyor Findings:

- No certified temperature and humidity instrument, nor a log to keep temperature and humidity.
- Digital monitors for temperature/humidity were not calibrated or checked by staff
- No written water quality procedure
- Humidity logs show levels below the established criteria; no corrective action documented.

Standard 06.02.01

Essential Conditions

Tips for compliance:

- Ensure that temperature and humidity monitoring equipment have in date calibrations.
- Educate staff on the importance of documenting corrective actions taken to correct out of range temperature or humidity readings.
- Develop a system to review temperature/humidity logs on a regular basis, at least monthly, so that lapses are identified, and appropriate corrective action measures taken. Document all review activities.
- Develop a policy to define what type of water (tap, reagent grade, sterile, distilled, Millipore system) is used for specific purposes.

Standard 06.02.03

Use of Reagents, etc.

Overview:

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

§493.1252(d)

Standard 06.02.03

Use of Reagents, etc.

Frequency: 13%

Comment: Deficiencies were cited when expired reagents were found or when open containers were not labeled with new expiration dates when opening affected expiration.

Examples of Surveyor Findings:

- QC records revealed that a kit was used 3 days beyond its expiration date.
- The Blood Bank saline in use did not have a new expiration date noted on the container. The manufacturer states open saline expires in 30 days.
- The laboratory did not ensure reagents were not used beyond their expiration as some reagents in use were found to be expired.

Standard 06.02.03

Use of Reagents, etc.

Tips for compliance:

- Periodically check inventory to make sure all materials are in date.
- If expiration dates change upon opening, verify that the new expiration date is on the open vial/material.
- Check for and dispose of materials that have evidence of contamination, drying, or other signs of deterioration.

Standard 06.03.00

Verification of Performance Specifications

Overview:

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate before reporting patients that it can obtain performance specifications comparable to the manufacturer for the following:

- Accuracy.
- Precision.
- Reportable range of test results for the test system.
- Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

§493.1253(a),(b)(1)(i-ii),(c)

Standard 06.03.00

Verification of Performance Specifications

Frequency: 12%

Comment: Deficiencies are cited when any of the required specifications are not verified, assessed, and approved by the laboratory director prior to reporting patients.

Examples of Surveyor Findings:

- Samples were run to determine accuracy, but no analysis of the data was done to verify the accuracy.
- There was no evidence that the medical director signed off on the validations.
- The laboratory did not establish age-related reference ranges for CBC elements.
- Results below the proven linearity range were not being reported as less than the linear range.

Standard 06.03.00

Verification of Performance Specifications

Tips for compliance:

- Develop a checklist to help ensure that all necessary performance characteristics were verified, reviewed, and documented prior to implementing a new test/test system.
- Include age and gender-specific reference ranges as needed that reflect your patient population.
- Verify the accuracy of diluted specimens
- Verify any LIS calculations for the new test.
- Verify that results are not reported outside the linear range.
- Be sure the Laboratory Director reviews and approves the verifications.

Standard 06.04.00

Maintenance Checks

Overview:

Equipment, instruments, or test system maintenance is performed as defined by the manufacturer and with at least the frequency specified by the manufacturer.

§493.1254(a)(1)

Standard 06.04.00

Maintenance Checks

Frequency: 18%

Comment: Deficiencies were cited when maintenance was not performed, not performed on schedule, or not appropriately documented.

Examples of Surveyor Findings:

- Document review showed that maintenance checks on equipment or instruments were inconsistently performed.
- A maintenance log was not maintained.

Standard 06.04.00

Maintenance Checks

Tips for compliance:

- Create a log to document all maintenance/testing as required by the manufacturer.
- Develop a system to ensure that each maintenance log is reviewed on a regular basis, at least monthly, so that lapses in maintenance can be identified and appropriate corrective action measures taken.
- Document all review activities.

Standard 06.08.01

Comparison of Test Results

Overview:

If the same test is performed using different methods or instruments, or at multiple locations, the laboratory must compare results twice a year and evaluate the relationship against written criteria for acceptable variation in test values.

All test result comparison activities must be documented.

§493.1281(a),(c)

Standard 06.08.01

Comparison of Test Results

Frequency: 21%

Comment: Deficiencies were cited for failure to perform comparison studies.

Examples of Surveyor Findings:

- Comparison studies were not performed between manual and automated differentials twice per year.
- Comparison studies were not performed on all I-Stat meters for back up chemistries using the Chem 8+ cartridges for glucose, BUN, creatinine, sodium, potassium, TCO₂, and chloride.
- Studies had been completed as required for the routine chemistry tests, but there were gaps in the correlation studies for the therapeutic drugs, ETOH, ammonia, CRP, and A1C.
- A comparison study between the Quick Vue serum HCG and the Vitros 5600 was not performed every six months.

Standard 06.08.01

Comparison of Test Results

Tips for compliance:

- Develop a list of tests that require comparison testing.
- Develop written procedures for performing comparison studies that include criteria for evaluation and acceptable performance.
- Develop a calendar/schedule to ensure that studies are completed twice each year.
- Take and document corrective actions if correlations fail to meet the acceptable performance stated in your policy.

Questions?





EDUCATIONAL RESOURCES

Thank you

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