POINT OF CARE TESTING
COMMON DEFICIENCY CITINGS-

Come to the party prepared.

Common Deficiencies During an Accreditation Inspection

Objectives-

- Identify 3 common causes for citings
- Identify 5 common categories of deficiencies cited during an inspection
- Review case examples and discuss options for response

Approved Inspecting agencies for Certificate of Accreditation and Compliance

- College of American Pathologists (CAP)
- The Joint Commission (TJC)
- COLA-commission on Office Laboratory Accreditation
- AABB-American Association of Blood Banks
- AOA-American Osteopathic Association
- ASHI-American Society for Histocompatibility and Immunogenics
- State Agency (For COC)

Three possible causes for a citation

Complete omission	Not aware that the requirement exists, so no plan in place.
Incomplete documentation or unable to retrieve documentation	Retrieval of supporting documentation is crucial to a successful outcome. Staff may not be available who know where data lives.
Discrepancy between policy and performance	Day to day processes do not reflect the content of existing policy that has been created, as processes change, policy is not updated.

Common Citings during inspection process

CAP

1. GEN.55500	Competency Assessment
2. COM.04250 COM.40000	Comparability of Instruments Method Validation
3. COM.01700	PT Evaluation
4. DRA.11425	Director Responsibility-Delegation of Functions
5 COM.04200	Instrument/Equipment Record Review

TJC

1. HR.01.06.01	Staff are competent
2. QSA.02.08.01 QSA.02.03.01	Method comparisons Calibration Verification
3. QSA.01.03.01	Proficiency sample handling and testing and documentation
4 LD.04.05.07	Performance of Duties, LD, TC, TS
5. QSA.02.10.01	Quality Control

COMPETENCY ASSESSMENT-

Waived Testing -Requires initial orientation then annual competency. Variations in testing from one location to another must be reviewed with competency.

Non-Waived Testing -Requires initial orientation, semiannually during the first year and annually thereafter.

There are 6 components that need to be evaluated.

Competency must be assessed where testing is performed. (CAP/CLIA Number)

Qualifications to Assess Competency- waived vs non-waived

Documentation-Training for each test is documented and retrievable.

Applicable standards:

CAP

GEN.55450 Personnel Training
GEN.55499 Waived Testing Assessment
GEN.55500 Non-waived Testing
GEN.55510 Qualifications to Assess Competency
POC.06800 Authorized Personnel
POC.06850 Personnel Training
POC.06875 Waived Testing Assessment
POC.06910 Non-waived Testing Assessment
POC.06920 Qualifications to Assess Competency

JC

WT.03.01.01.01 Designation of staff to assess competency
WT.03.01.01.02 Orientation training is required for waived testing.
WT.03.01.01.03 Training is completed and documented.
WT.03.01.01.04 Training on the use and maintenance of instrumentation.
WT.03.01.01.05 Methods to assess competency
WT.03.01.01.06 Frequency of competency

Citation-

GEN.55500 - Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system.

The skill validation form included the option to use NA (not applicable) as a choice. There were some elements that staff felt did not apply to all users.

Have you determined how your team will assess all 6 elements?
Is your documentation process clear?

Elements of competency assessment include but are not limited to:

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

Citation:

POC.06910- Competency assessment of non-waived testing - no semi-annual competency completed.

How are you documenting the semi-annual competency?

Proficiency testing - Evaluation of participant (laboratory or individual) performance against pre-established criteria by means of interlaboratory comparisons.

Citation: COM.1700 PT Assessment. Evaluation had failures and not documentation of a resolution.

Citation: COM.01400 PT Attestation Statement not signed.

Method validation Performing a series of experiments designed to identify certain types of analytical errors. Looking at platform performance and reliability of results.

Calibration- A **calibration** indicates the error of the instrument and compensates for any lack of trueness by applying a correction. It is the process of testing and adjusting the instrument to establish a correlation between the measurement of the substance and the actual concentration of the substance.

A **Calibration verification** (Cal/Ver) is testing materials of known concentrations to assure that the test system is accurately measuring samples throughout the reportable range. This can indicate that the measurement error is smaller than a so called maximum permissible error.

AMR-the analytical measuring range of an instrument, without dilution or manipulation.

Quality Control Assayed or un-assayed products used to monitor an analysis performance within desired limits.

Total allowable error- the amount of error that is allowable for imprecision and bias, without invalidating the interpretation of a test result.

Data Innovations Allowable Total Error Table

Glucose

Analyte	Fluid	Method	Limit	Source
Glucose			+/- 6 mg/dL or +/- 10% (greater)	1 CLIA, 2 WLSH, 3 NYS, 6 AAB
Glucose		Radiometer 725	10% or 6 mg/dL (greater)	4 CAP
Glucose		AU640	10% or 6 mg/dL (greater)	4 CAP
Glucose	S-		6.3%	5 BV
Glucose			0.5 mmol/L, 10%	7 RCPA

Method Validation and Verification Approval COM.40000 –

Requirement-For each non-waived test, there is an evaluation of the test method validation or verification study (accuracy, COM.40300 precision COM.40310 COM.40600 reportable range.) signed by the laboratory director or designee meeting CAP director qualifications.-

Calibration verification aka (AMR)- POC.08600 AMR Verification Criteria

Requirement-Criteria are established for verifying the analytical measurement range (AMR), and compliance is recorded.

Method Comparisons- Non-waived Testing COM.04250

Requirement-If the laboratory uses more than one non-waived instrument/method to test for a given analyte, the instruments and methods are checked against each other at least twice a year for comparability of results.

CAP Citation

COM.04250-No comparisons to lab methods for tests on AVOX and iSTAT.

- While the facility did have a policy for this process, they were unable to locate it, and they did not follow the required schedule for platform comparisons.

DRA.11425 Director Responsibility-Delegation of Functions.

If specific laboratory director functions or responsibilities are delegated, the delegation is in writing (by name or job title) and the director ensures that the functions or responsibilities are properly performed by a qualified individual.

CAP citations

DRA.11425 Delegation to perform competency assessments was not documented for staff members....

POC.06920 Qualifications of individuals assessing competency-staff are not qualified to evaluate competency for level of testing

POC.07550 Quality control review not documented. Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

COM.04200 Instrument/Equipment Record Review Instrument and equipment maintenance and function check records are reviewed and assessed at least monthly by the lab director or designee.

Questions?

Resources

AACC July 2018 Laboratory Top Deficiencies
www.aacc.org/publications/cln/articles/2018/july/top-laboratory-deficiencies-across-accreditation-agencies
CAP Checklists 8/22/18- cap.org
JC Waived Chapter- https://e-dition.jcrinc.com/MainContent.aspx
CMS Guidelines- cms.gov
Westgard QC- westgard.com
Data Innovations- datainnovations.com