Frequent Citations

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COLA v. 04.05.19

COLA – Frequent Citations

Criteria	COLA Requirement	Things that may trigger a citation
ORG3	Do you notify COLA within 30 days of any changes to test menu and personnel and have you authorized your PT scores to be sent to COLA?	Not updating personnel, test menu, ATV; lab has not sent authorization for release of PT results
ORG9	Does the laboratory have a procedure for the FDA voluntary reporting of device-related adverse events?	No procedure
ORG10	Does the laboratory have documented education of its personnel in the FDA procedure for voluntary reporting of device-related injuries and/or malfunctions?	No documentation of training on the procedure
ORG14	Do personnel follow all procedures as written in the procedure manual?	Personnel not following procedures usually seen with specimen collection and handling; not following centrifugation requirements for coagulation or urine sediment samples
FAC14	Do you have a written bloodborne pathogens exposure control plan and do all applicable employees receive annual training on the plan?	lack of annual training
LDR1	Does the Laboratory Director meet the General Responsibilities of the position?	systemic issues; numerous repeat citations

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LDR2	Does the Laboratory Director meet the Procedural Responsibilities of the position?	Incomplete procedures; no annual SOP reviews
LDR4	Does the Laboratory Director meet the Proficiency Testing Responsibilities of the position?	unsigned attestations; no PT enrollment; consistent unsuccessful PT events; missed submission of PT; no review of PT; lack of corrective action for PT
LDR5	Does the Laboratory Director meet the Quality Control and Quality Assessment Responsibilities of the position?	Ineffective QC or QA reviews, no QA plan, QA not implemented, systemic QC issues, no QC reviews, QC reviews not performed in timely manner; QC not performed as required
PER1	Is there a written job description for each employee that describes individual duties and responsibilities?	No written job descriptions for Lab Director, Clinical Consultant, Technical Supervisor, Technical Consultant, Technical Supervisor, Testing personnel, Lab assistants, etc.
PER3	Does the personnel file contain documentation of the person's education and experience that qualifies them for the position they hold in the laboratory?	no documentation of education or training; foreign degrees not evaluated for US equivalency

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PER4	Does each laboratory employee adequately fulfill the responsibilities for the position(s) they hold?	This criteria is broken down into 3 segments to individually address the Technical Consultant/Technical Supervisor; General Supervisor; and Testing personnel. Duties not met include **TC/TS**: not verifying instrumentation; incomplete or non compliant QC plan, no enrollment in PT; no competency assessments performed on testing personnel; lab reporting results with out of range QC. **GS**: not performing competency assessments on testing personnel, not adequate oversight of the laboratory. **Testing personnel:** not handle PT like patient samples, not performing QC or QC corrective action; not performing calibrations or instrument maintenance as required; not following manufacturer requirements
PER5	Does your director or Technical Supervisor/Technical Consultant follow written policies and procedures to periodically evaluate personnel performance and competency of all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation?	Competency assessments not performed; not done at six months, one year, and annual frequency; performed by individuals not qualified as TC or higher; ineffective reviews
PER6	Do the personnel reviews include the person's continuing education?	No continuing education performed

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PT2	For each regulated analyte tested in your laboratory, do you perform and report PT results to the PT program for all events, unless you have been granted an exemption by the PT program and COLA for voluntarily ceasing to test an analyte?	Missed PT event
PT5	Do you follow the same procedures for testing PT samples as you do for patient specimens?	not rotating challenges among all testing personnel; repeating samples when it does not meet repeat criteria; calibrating right before running samples
PT8	Are all PT results reviewed and evaluated by the laboratory director or other qualified designee in a timely manner?	No review by LD or qualified individual; no date of review; date of review greater than 30 days after receipt of results
PT9	When PT results are unsatisfactory, do you evaluate the results and take appropriate corrective action?	no corrective action documented; corrective action only includes repeats but no evaluation of patient impact or investigation into root cause
PT10	Does your laboratory verify the accuracy of any analyte, specialty, or subspecialty that is assigned a PT score that does not reflect the accuracy of the laboratory's actual test performance?	No evaluation of non graded PT results

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PT15	A copy of the attestation form signed by the director and the testing personnel?	Attestations either missing or not signed
PT16	An indication of the review of the graded PT results by the director as well as the supervisory and testing personnel?	No indication that PT results are reviewed by laboratory staff such as Consultants, Supervisors, or testing personnel
PRE17	Are all specimens labeled with a unique patient identifier composed of 2 individual identifiers, and the source of the specimen (when appropriate)?	Often seen on urine samples or microtainer samples
MA2	Are specimens, reagents, standards, and controls stored as directed by their manufacturer or other reliable source such as a laboratory textbook?	Not stored in a manner that meets manufacturer requirements; commonly an issue with freezer temperatures
MA4	Are reagents, controls, standards, calibrators, kits, and media properly discarded when they exceed their expiration dates?	often seen with vacutainer tubes which are not often used; stain; KOH; and low volume testing
MA14	Have acceptable ranges for temperature been established for each of the above?	Temperature ranges either not established or do not meet the requirements for the lab

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MA16	Does the laboratory take and document all corrective actions taken when storage conditions are not maintained within established limits?	No corrective action for out of range temperatures
MA21	Is preventive maintenance performed and recorded for daily, weekly, monthly, semi-annual, and annual maintenance as required by the manufacturer?	maintenance not performed and documented at required frequency
CA1	For all non-waived tests and methods, as applicable, is calibration performed at the frequency recommended by the manufacturer or at the frequency determined by the laboratory if more stringent than the manufacturer?	Calibration not performed at required frequency; very common with hematology analyzers
CA2	Is calibration verification performed, according to the manufacturer's instructions including: • the number, type and concentration of materials to be used, • use of materials at low, medium and high values within the reportable range, as determined by the laboratory, • acceptable limits for calibration verification, once every six months or more often if required by laboratory procedures?	Calibration verification not performed; performance exceeds six months; does not cover reasonable reportable range; does not include three levels

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QC8	Are the materials used as controls verified by repetitive testing to meet the manufacturer's established parameters for mean and standard deviation?	not verify new lots of QC by running in parallel testing with current lot of QC for five days
QC10	Are manufacturer's instructions for the use of reagents, controls, and kits followed?	Labs not following manufacturer requirement; not centrifuging turbid urines if required for drug screening; not establishing their own mean and SD for QC; any variations from package inserts or manufacturer such as incubation times, dilutions, specimen type or specimen handling; elimination or addition of procedural step; altering calibration process; etc
QC16	For each quantitative test performed, are quality control data prepared and plotted with each testing event, or are statistical parameters calculated to permit the laboratory to assess continued accuracy and precision of the method?	either no LJ graphs or statistics or often seen when no documentation of review every 5-7 data points
QC28	Does the laboratory director or qualified designee regularly review the quality control data with laboratory personnel?	Monthly QC reviews not performed or documented

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HE4	If you perform automated differential counts, have criteria been established for when a manual cell count must be performed to verify the automated count?	Lab has not established criteria
QA3	Do your Quality Assessment reviews enable the laboratory to identify and correct problems?	QA reviews have not been effective; have not identified or addressed issues
QA17.1	Accuracy and precision of the data entry process, whether manual or automated?	Not performed; not include both manual and automated tests; not include all steps such as raw data to LIS to EMR
QA17.2	Correctness of computer calculations performed on patient data?	Not verifying correctness of calculations