CLIA Updates

Summer 2018

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INR-Calculate a Normal Patient Mean Time

Accurate calculation of patient International Normalized Ratio (INR) requires using the correct normal patient mean time (established by each lab with each new lot) and the correct International Sensitivity Index (ISI) for each new lot of thromboplastin reagent. Incorrect calculation has been in the Montana top ten deficiencies of 2016 and 2017 and is on track to be in the most cited list again in 2018.

A previous newsletter emphasized an INR and ISI quality assurance monitor. Remember to also establish a new normal patient mean time with each new lot of thromboplastin reagent! The data for this calculation must be retained by the laboratory for at least two years.

The manufacturer's instructions for thromboplastin require labs to calculate a new patient mean with each new lot of thromboplastin reagents. When the lab receives a new lot, normal patients must be tested and the results used to calculate a new patient mean for each new lot. Remember to enter this new patient mean value and the new ISI into the analyzer or lab information system (LIS), so a correct INR will be calculated. Keep the data for at least two years! An ongoing quality assurance (QA) monitor to manually check the INR calculation would be a good reminder for the lab to ensure the correct ISI and patient normal mean were entered in the analyzer or LIS.

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New Website!

The State of Montana CLIA Program has a newly updated website! See the website at: http://dphhs.mt.gov/qad/Certification/CLIA

For Certificates of Compliance, the survey forms will no longer be emailed to the lab. An email with the letter announcing the survey and the link to the new website will be emailed to the lab after the survey is scheduled. If you have any trouble downloading the forms, please contact the CLIA Program.

Checking Calculations, Interfaces, and Manual Entry

The test report regulations include ensuring test results are accurate from the point of data entry (i.e. analyzer/personnel) to the report destination (i.e. provider/patient).

- 42 CFR §493.1291(a) Test Report (D5801)
  The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:
  (a)(1) Results reported from calculated data.
  (a)(2) Results and patient-specific data electronically reported to network or interfaced systems.
  (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

Quality assurance monitors document compliance with this regulation.

The first subsection requires verification of analyzers which auto-calculate results and are reported on the test report. The lab is responsible for ensuring calculations are accurately calculated by the analyzer. Use a calculator and verify the analyzers correctly calculate results. Document the calculation verification.

Examples of common calculations to verify include the International Normalized Ratio (INR), chemistry tests (i.e. glomerular filtration rate (GFR), albumin/globulin ratios, anion gaps, microalbumin/creatinine ratio), and calculated hematology tests (i.e. mean corpuscular volume (MCV) and red cell distribution width (RDW)). Consult the operator's manual for guidance on measured verses calculated parameters for each analyzer.

The second subsection questions whether both calculated and measured results are reliably sent from the analyzer to the laboratory information system (LIS) and electronic health record (EMR). Interface problems between analyzers and the computer programs are frequent and prevalent. Verify and document the values on the analyzers match the values reported in the LIS and EMR.

The third subsection requires laboratories to ensure manually transcribed results and reference laboratory results are also accurately entered in the LIS and EMR. Entry double verification and patient reviews are common assurance monitors to prevent manual entry errors.

Quality assurance monitors to verify calculations, check interfaces, and check for manual transcription errors will document compliance with this regulation.

Most Frequently Cited - 2017

Successful participation in proficiency testing took the top place for the most cited deficiency in the 2017 calendar year for Montana labs that failed two of three proficiency events for a regulated analyte. This was followed by quality control (QC) deficiencies, not following manufacturer directions, and unmet retention requirements.

- 42 CFR §493.803 Successful Participation (D2016)
  (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

- 42 CFR §493.1256 Control procedures (D5449)
  (d)(3)(ii) At least once each day patient specimens are assayed or examined, perform the following for - Each qualitative procedure, include a negative and positive control material.

- 42 CFR §493.1256 Control procedures (D5477)
  (e)(4) Before, or concurrent with the initial use--
  (e)(4)(i) Check each batch of media for sterility if sterility is required for testing;
  (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and
  (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

D5411: Failure to follow manufacturer directions for calculation of the International Normalized Ratio (INR).

- 42 CFR §493.1252 Test systems, equipment, instruments, reagents, materials, and supplies (D5411)
  (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.

- 42 CFR §493.1105 Retention requirements (D3031)
  (a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§493.1252 through 493.1289 for at least 2 years.

Other themes in the most cited list included failure to perform accuracy verification, procedure manual citations, quality control, and cytology citations.

INR–Calculate a Normal Patient Mean continued from page1

The CMS Interpretive Guidelines list the regulatory expectations for labs.

42 CFR §493.1269(b) INR Calculation
The INR is equal to the ratio of the patient's PT (in seconds) to the laboratory's established normal mean PT (in seconds), then raised to the power of the ISI. NOTE: A scientific calculator is needed to calculate the INR.

$$\textbf{INR} = (\textbf{Patient PT} \div \textbf{Mean Normal Range PT})^{\textbf{ISI}}$$

For INR calculations, **ensure** the laboratory:

1) Establishes a normal patient Prothrombin time mean with each new thromboplastin lot number;

2) Verifies that the normal patient Prothrombin time mean study has been performed according to the manufacturer's instructions;

3) Incorporates the current and pertinent normal patient Prothrombin time mean and ISI value for each lot of thromboplastin into the analyzer/LIS;

4) Documents the manual check of the INR calculation for each new lot number;

5) Documents each thromboplastin lot number, with the normal patient Prothrombin time mean and the ISI value provided by the manufacturer;

6) Periodically verifies, for each thromboplastin lot number in use, the correct normal patient Prothrombin time mean and the International Sensitivity Index (ISI) value are being used for calculating the INR value; and

7) Periodically verifies the accuracy of the INR calculation.

Susceptibility Breakpoint Website

The Food and Drug Administration (FDA) released a new webpage with current, up to date information on susceptibility interpretation criteria for bacteria and fungi. This website will be maintained for changes in breakpoint criteria over time. Labs may reference this website for managing breakpoints for susceptibility testing.

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm

Questions and Answers (Q & A)

Q: Can nurses perform microscope tests for a CLIA Certificate of Provider Performed Microscopy Procedures (PPMP)?

A: For a Certificate of PPMP, nurses do not qualify to perform microscope tests. 42 CFR §493.1363 lists the testing personnel for PPMP certificates as state licensed physicians, midlevel practitioners, or dentists. Personnel who are not physicians, midlevels, or dentists do not qualify to perform the microscope testing for a Certificate of PPMP.

However, nurses can qualify as testing personnel to perform microscope tests for a CLIA Certificate of Compliance or Accreditation.

Q: Do you have any resources for the PPMP regulatory expectations that I can give to clinics asking about the requirements?

A: The CDC PPMP booklet is a great resource for Certificate of PPMP information. Download it at https://wwwn.cdc.gov/clia/Resources/PPMP/.

Q: How long do I keep lab documentation?

A: The record retention requirements are at 42 CFR §493.1105, including the expected retention of test requisitions, test procedures, quality control, patient test records, analytic system records, calibrations, method verification, proficiency testing, quality assessment, and test reports. The retention requirements are longer for blood bank records, cytology and histopathology slides, blocks, and pathology reports. Please check the regulations prior to cleaning out any binders, cupboards, or storage units to make sure the lab retains documentation per the regulations.

Q: Can I scan/email or fax the proficiency testing attestation statements to my offsite Laboratory Director to sign?

A: Yes, it is acceptable to email or fax the attestation statements to the Laboratory Director to sign. The laboratory will need to keep track of the documents to ensure the signed forms are returned, but this is an option to ensure the attestation statements are signed in a timely manner.

References:
CMS CLIA Interpretive Guidelines
CMS CLIA Federal Regulations
S&C Letters/QSO Letters

If you would like to be added to the emailing list for future correspondence from the Montana CLIA program, please send an email to Joyce Shepard at jshepard@mt.gov.

Questions about the information discussed in this CLIA Update?

The Montana CLIA Program would love to answer them. Contact us at:

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