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eGFR Discussion

Most major commercial manufacturers are using calibrators that are now traceable to IDMS with the exception of the Siemens Diagnostics Dimension analyzer, which produces values that are similar to those from IDMS-traceable calibrations. Participants were asked to identify their calibration type (traditional or IDMS). Some participants are continuing to use the traditional MDRD equation, which will produce eGFR values that are 5 to 10% too high when using IDMS-traceable calibrators. This occurs because the traditional calibration method that was used to derive the MDRD equation was biased high. The Laboratory Working Group of the NKDEP recommends that laboratories implement the MDRD equation to estimate GFR.

Some participants may be using a more recently reported equation, CKD-EPI (see Levey AS, Stevens LA, Schmid CH, et al. A new equation to estimate glomerular filtration rate. *Ann Intern Med*. 2009;150:604-12). At this time, the NKDEP has not yet formally recommended adoption of the CKD-EPI equation. The CKD-EPI equation provides improved estimates of GFR in patients with higher GFRs than does the MDRD equation.

eGFR Calculations

Participants calculated the eGFR using their first result for specimens LN24-03 and LN24-04. The following table shows the percentage of laboratories that reported an eGFR that was within the acceptable range. Calculations of eGFR within ±1 mL/min/1.73 m^2 were deemed acceptable.

LN24-03			
Equation	Calibration Type	Acceptable	Unacceptable
MDRD	IDMS-Traceable	141	10
	Traditional	21	7
CKD-EPI	IDMS-Traceable	32	4
LN24-04			
Equation	Calibration Type	Acceptable	Unacceptable
MDRD	IDMS-Traceable	141	10
	Traditional	22	6
CKD-EPI	IDMS-Traceable	28	8

LN24-03 was reported to be from a 56-year-old non-African American male. If the laboratory determined the creatinine to be 2.030 mg/dL using an IDMS-traceable method, the eGFR should be 34 mL/min/1.73 m2 (MDRD equation) or 36 mL/min/1.73 m2 (CKD-EPI equation).

LN24-04 was reported to be from a 26-year-old African American female. If the laboratory determined the creatinine to be 2.692 mg/dL using an IDMS-traceable method, the eGFR should be 26 mL/min/1.73 m2 (MDRD equation) or 27 mL/min/1.73 m2 (CKD-EPI equation).

Laboratories with an unacceptable result for eGFR calculation should investigate the source of error and correct it.

The Instrumentation Resource Committee will be revising the evaluation criteria as new information becomes available. Please direct any comments, questions, or suggestions to Sharon Burr at 800-323-4040, extension 7417 or e-mail sburr@cap.org. Again, thank you for your participation in this accuracy-based CAP Calibration Verification/Linearity Survey.

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Additional Challenge Results Discussion

As part of theCAP's 2014 LN24-B Survey, we asked interested laboratories to measure four additional analytes in the LN24-01 specimen: calcium, albumin, total protein, and glucose. This specimen is pooled off-the-clot, fresh frozen serum without any additional supplements or stabilizer. As such we anticipate that measurement procedure results would be fairly representative of how the various measurement procedures perform that are currently being used in clinical laboratories would perform with using actual clinical samples. As patients are more frequently seen in a variety of clinical settings often using different measurement procedures and with patient result being compared to literature-derived decision points that are not measurement procedure-specific, comparability of reported laboratory results becomes increasingly important (1). One of the more difficult and potentially costly aspects in achieving harmonization of clinical laboratory results is the testing of the degree of harmonization that has actually been achieved in the field. Accuracy-based CAP Surveys are one of the major and quite useful sources of data regarding the comparability of a given laboratory's results with other laboratories, but testing accuracy of measurement procedures in the field is a fairly costly and time consuming proposition when done on an analyte-by-analyte basis. This pilot of these four analytes in the LN Survey was aimed at assessing the possible use of an existing CAP Survey's material for developing data on a variety of measurement procedures in the field.

We were very gratified that a reasonably large percentage of laboratories volunteered to submit data, giving us substantial information most of the more popular measurement procedures being used today for these four analytes. Upon quick review of the data, several general observations can be made. For albumin, the bromcresol purple dye-binding measurement procedures appear to give on average 5% lower values than bromcresol green dye-based procedures, although some specific manufacture's procedures (e.g., OCD Vitros) seem to be exceptions to this generalization. For calcium, there seems to be no general major methodological principal-based bias, but a few specific IVD manufacturer's procedures (e.g., Siemens Dimension Vista) seem to give values significantly lower from most others. For calcium, overall the various methodological principles seem to give values that are quite close to each other, although some specific IVD manufacturer's measurement (e.g., Siemens Dimension Vista) procedures seem to give results that are statistically different from the others. For glucose, glucose oxidase-based measurement procedures appear to give values a few percent low compared to hexokinase-based measurement procedures. Some have argued that since one of the main reference measurement procedures for glucose is hexokinase-based, measurement procedures using it should give more accurate results. However, those making this argument must be reminded that the hexokinase-based reference measurement procedures for glucose use a protein free filtrate of serum, not serum directly. We must point out that unlike creatinine, for the LN24 Survey samples we

have no reference measurement procedure determined values for any of these four analytes in the pilot, so one must be very cautions inferring which specific IVD manufacturer's measurement procedures or methodological approaches are in fact more accurate. The CAP's Instrumentation, Chemistry, and Accuracy Based committees are be exploring various ways to foster the harmonization process and will be discussing various ideas over the coming months including the general approach used in this pilot. Any ideas from participants in this pilot have ideas would be very welcome and should they should be addressed to sburr@cap.org.

Additional Challenge Results Discussion, cont'd.

1. Miller WG, Myers GL, Gantzer ML, et al. Roadmap for Harmonization of Clinical Laboratory
Measurement Procedures. *Clinical Chemistry* 2011; 51:1108-17.

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