RESULTS REPORTING

Inspector Instructions:

	• Sampling of reporting policies and procedures • Sampling of patient reports (reference interval and cut offs included)
	• How is information on the equations used for calculating eGFR and LDL results communicated to clinicians?

*****NEW** 12/26/2024***

CHM.15225 eGFR and LDL Cholesterol Calculated Test Results **Phase I**

Clinicians have access to information regarding the equation used to calculate results for estimated glomerular filtration rates (eGFR) and low-density lipoprotein (LDL) cholesterol.

NOTE: Calculated results may differ based on which equation is used. This may limit clinical assessment of results and/or comparability of calculated results across laboratories, particularly when the source equation is not readily available to providers.

The information can be made available to clinicians using different approaches, such as on the patient report, test reference guide, or inclusion of the equation name in the test name.

Evidence of Compliance:

✓ Patient reports with information on the calculation used **OR**
✓ Test reference guide or other mechanism for providing calculation information

REFERENCES

1) Inker LA, Eneanya ND, Coresh J, et al. New Creatinine- and Cystatin C-Based Equations to Estimate GFR without Race. *N Engl J Med.* 2021; 385(19):1737-49.
2) Sampson M, Ling C, Sun Qian, et al. A New Equation for Calculation of Low-Density Cholesterol in Patient With Normolipidemia and/or Hypertriglyceridemia. *JAMA Cardiol.* 2020; 5(5):540-48.

CHM.15250 Toxicology Results **Phase II**

The laboratory follows written procedures for the reporting of toxicology results.

NOTE: In addition to the requirements found in the Laboratory General Checklist, the following information must be included in toxicology reports:

1. *If appropriate, substances or classes of substances analyzed as part of the toxicology test*
2. *Specimen type*
3. *Report status for positive results (ie, unconfirmed, confirmed or pending confirmation)*
4. *For immunoassays, the assay cut-off concentration for each drug or drug class**
5. *If the report includes unconfirmed screening results, a statement that such results are to be used only for medical (ie, treatment) purposes. Unconfirmed screening results must not be used for non-medical purposes (eg, employment testing)*

**The cut-off concentrations may either be included in the report or in a separate chart/ memorandum available to clinicians.*

Laboratories are encouraged to identify the detected drugs as parent compounds, metabolites, or impurities of drugs in the report or in a separate chart/memorandum available to clinicians.

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory.* 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

METHODS, INSTRUMENT SYSTEMS, AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

- If problems are identified during the review of the methods, instrument systems, and equipment or when asking questions, further evaluate the laboratory's responses, corrective actions and resolutions
- Select a representative assay and follow the entire process from specimen receipt to final result reporting

RADIOIMMUNOASSAYS

Refer to the Laboratory General Checklist for requirements for use and storage of radioactive materials.

Inspector Instructions:

- Sampling of radioimmunoassay policies and procedures
- Sampling of calibration records
- Sampling of background radioactivity records

CHM.15900 Gamma Counter Calibration **Phase II**

Gamma counters and/or scintillation counters are calibrated, with the results recorded and compared to previous values each day of use.

Evidence of Compliance:
✓ Records of calibration

CHM.16000 Background Radioactivity **Phase II**

The background radioactivity is determined each day of use, including the background in each well of a multi-well counter, with defined upper limits of acceptability.

Evidence of Compliance:
✓ Records of background radioactivity determinations at defined frequency

CHM.16200 Counting Times **Phase II**

The laboratory defines counting times for quantitative procedures that are sufficiently long for statistical accuracy and precision.

REFERENCES
1) Klee G, Post G. Effect of counting errors on immunoassay precision. *Clin Chem.* 1989;35:1362-1366

CHROMATOGRAPHY AND MASS SPECTROMETRY

THIN LAYER CHROMATOGRAPHY (TLC)

Inspector Instructions:

- Sampling of TLC policies and procedures
- Sampling of control, standards/calibrator records

CHM.16300 Standard/Calibration Materials **Phase II**

Appropriate standards, calibrators, or controls (as applicable) are included with each TLC plate.

NOTE: Appropriate standards must include compounds that test the chromatographic range of the TLC plate, and that test all phases of the staining/development system. This may consist of a standard, previously tested positive patient sample, or dot that contains appropriate compounds.

Evidence of Compliance:

✓ Records showing use of appropriate standards/calibrators with each plate

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory.* 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

CHM.16400 Daily QC - TLC **Phase II**

Negative and appropriate positive controls are extracted and run through the entire procedure.

NOTE: Positive and negative controls must be extracted and carried through the entire procedure with each plate or card.

Appropriate positive controls must include drugs/compounds that test the extraction, chromatographic range of the TLC plate, and the staining/development system.

Evidence of Compliance:

✓ QC records at defined frequency

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1256(d)(4)].
2) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory.* 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

CHM.16500 Solvent Mixtures **Phase II**

Solvent mixtures are prepared fresh as needed.

NOTE: If a mixture of solvents is used, certain components will evaporate with time faster than others. This leads to poor extraction or reproducibility of migration rates. If a commercial kit is used, the manufacturer's instructions should be followed.