INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a chemistry laboratory section or department.

Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.


Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

CHEMISTRY & TOXICOLOGY GENERAL ISSUES

PROFICIENCY TESTING

Inspector Instructions:

- Records of hemoglobin A1C accuracy-based proficiency testing results evaluation, as applicable

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

CHM.12925 Hemoglobin A1C Testing **Phase I**

For laboratories that use accuracy-based proficiency testing (PT) for hemoglobin A1C, the laboratory evaluates its results based on acceptable performance criteria of +/- 6% from the target value, with appropriate corrective action taken for each unacceptable result.

NOTE: The CAP recommends use of accuracy-based PT products, when possible, to evaluate the accuracy of hemoglobin A1C results. Due to limitations in product stability, this may not be available for laboratories outside of the US.

The Centers for Medicare and Medicaid Services (CMS) have established acceptable performance criteria for hemoglobin A1C as a regulated analyte at +/- 8% from the target value. The CAP and all CAP-accepted PT providers must use the +/- 8% criteria in the formal grading of the PT for reporting non-waived results to the CMS. For laboratories participating in the CAP's accuracy-based PT program for hemoglobin A1C, the CAP will also evaluate their results against the target value using +/- 6% performance criteria. This is provided in the participant evaluation

and participant summary report. Laboratories must review their performance against the +/- 6% criteria and perform corrective action for each unacceptable result.

Evidence of Compliance:

✓ Records of accuracy-based PT evaluation using the +/- 6% performance criteria

REFERENCES

1) Sacks DB, Arnold M, Bakris GL, et al. Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus. *Clin Chem*. 2023; 69(8):808-68.

QUALITY MANAGEMENT

CALIBRATION AND STANDARDS

Inspector Instructions:

	• Sampling of calibration and AMR policies and procedures • Sampling of calibration/calibration verification records • Sampling of AMR verification records • Sampling of patient reports and worksheets for verification of results outside of AMR • Current DEA license (for US laboratories that handle pure controlled substance(s))
	• Sampling of calibration materials (quality)
	• What is your course of action if calibration is unacceptable? • When was the last time you performed a calibration procedure and how did you verify the calibration? • What is your course of action when results fall outside the AMR? • What is your course of action when you receive calibration materials for non-FDA cleared/ approved assays? • How does your laboratory verify concentration techniques?
	• Further evaluate the responses, corrective actions, and resolutions for unacceptable calibration, and unacceptable calibration verification

CALIBRATION AND VERIFICATION PROCESSES – WAIVED TESTS

CHM.12950 Calibration, Calibration/Verification - Waived Tests **Phase II**

For waived tests, testing personnel follow manufacturer's instructions for calibration, calibration verification, and related functions.

Evidence of Compliance:

✓ Records for calibration/calibration verification/related functions as required by the manufacturer **AND**