Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	25D0029702	11/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Merit Health Madison Hospital Laboratory	161 River Oaks Dr, Canton, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's Policies and Procedures Manual, laboratory personnel records and an interview with the technical consultant/technical supervisor /general supervisor (TC/TS/GS) #1 as listed on the Centers of Medicare and Medicaid Services (CMS) 209 form at 4:00 p.m. on 11/29/2023, the laboratory failed to establish written policies and procedures to assess competency of those individuals acting as TC, TS, and GS. Findings include: 1. Based on surveyor review of the laboratory's Policies and Procedures Manual there were no written policies and procedures for assessing competency of technical consultants, technical supervisors or general supervisors available for review. 2. Based on surveyor review of the laboratory personnel records for 2022 and 2023, there were no competency assessments available for review for the TC, TS or GS positions. 3. TC/TS/GS #1 in an interview at 4:00 p.m. on 11/29/2023 confirmed there was no policy established by the laboratory to assess the competency of technical consultants, technical supervisors or general supervisors and there were no competency assessments performed for these positions.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the review of Siemens Dimension records to include assay package inserts, procedures, and calibration records from 11/1/2021 through 11/30/2023 and confirmation from the laboratory manager during an interview at 2:00 p.m. on 11/30/2023, the laboratory failed to perform calibration verification on the Siemens Dimension EXL-LM (serial number 801) and Dimension EXL-200 (serial number 853) every 6 months for sodium (Na), potassium (K), chloride (Cl) and Hemoglobin A1C (HbA1c). There were 0 of 4 expected calibration verifications documented as performed. Findings include: 1. Review of the Siemens Dimension procedures indicated that Na, K, Cl, and HbA1c are calibrated using less than 3 calibrator levels. 2. Calibration verification is required every 6 months on assays that are calibrated with less than 3 calibrator levels. 3. Review of the Siemens Dimension EXL 200 (SN 853) calibration records revealed no records of calibration verification on Na, K, and Cl for 2021, 2022, or 2023 (0 of 4 expected verifications documented as performed). 4. Review of the Siemens Dimension EXL-LM (SN 801) calibration records revealed no records of calibration verification on Na, K, Cl or HbA1c for 2021, 2022, or 2023 (0 of 4 expected verifications documented as performed). 5. The laboratory manager confirmed in an interview at 2:00 p.m. on 11/30/2023 that calibration verifications had not been performed for Na, K, Cl, or HbA1c for the Siemens Dimension EXL-LM and EXL-200.