Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2116823	08/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Madison Core Laboratories	2705 Artie St Sw Bldg 400 Suite 25, Huntsville, AL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) and College of American Pathologist (CAP) Proficiency Testing (PT) records and an interview with the Technical Supervisor (TS), the Laboratory Director failed to sign the PT attestation statements for the specialties in Immunology, Chemistry, and Microbiology. This was noted for 6 of 31 events reviewed in 2024 through 2025. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2024 Chemistry 1st Event. b) 2024 Chemistry Miscellaneous 2nd Event. c) 2024 Immunology 2nd Event. d) 2024 Immunology 3rd Event. e) 2025 Immunology 1st Event. 2. A review of the CAP PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for 2024 Microbiology MC3-C. 3. During an interview on 8/13/25, at 1:06 PM, the TS confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 a review of the Cobas 6000 calibration verification (C-V) records and an interview with the Technical Supervisor, the laboratory failed to ensure C-V was performed and documented on the Cobas 6000 Chemistry / Immunoassay analyzer the first half of 2024 and Gabapentin and Urine Protein the second half of 2024. The findings include: 1. A review of the C-V records for the Cobas 6000 Chemistry / Immunoassay analyzer revealed no evidence of C-V documentation for the first half of 2024. Gabapentin and Urine Protein C-V documentation was also missing for the second half of 2024. 2. During an interview on 8/13/2025 at 2:00 PM, both Technical Supervisors stated the C-V could have been missed due to personnel turnover.