Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2128876	07/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Scarborough Family Medicine, Llc	4226 Hartley Bridge Road, Suite 103, Macon, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 07, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 maintenance records review and staff interviews, the laboratory failed to perform and document ALL equipment maintenance checks for the Cell-Dyn Emmerald Hematology analyzer as required by the instrument manufacturer every six months in 2024 and 2025. Findings: 1. A review of the Cell-Dyn Emmerald

	Hematology analyzer maintenance logs revealed that intrument calibration was performed once in 2024 (06/27/2024) and once in 2025 (11/07/2025) instead of twice annually. 2. An interview with the laboratory coordinator TP#2 (CMS 209) , at approximately 11:45 AM, in the break review room. confirmed that calibration was performed once annually in 2024 and 2025.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on maintenance document review and interview with staff, the laboratory director failed to ensure that all phases of quality testing (preanalytic, analytic and post analytic) guidelines were followed to identify and fix problems in the laboratory from June 2024 - November 2025 as required by the Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Quality Assurance (QA) documents review revealed the laboratory director, who is also the technical consultant (TC), failed to ensure ALL monthly maintenace checklists, to identify and fix problems in the laboratory from June 2024 - November 2025, were followed. 2. Bi-annual instrument calibrations for the Cell-Dyn Emmerald Hematology analyzer was done only once in 2024 and once in 2025. 3. An interview with the lab coordinator (TP#2 on form CMS 209) in the break review room on 07/07/2026 at approximately 11:20 AM, confirmed the lab director failed to ensure proper oversight of the laboratory from June 2024 - November 2025.