Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2128876	08/11/2022
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 August 11, 2022.. 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:
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 laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow a policy and procedure to assess Testing Personnel(TP) competency as required for Hematology. The Findings include: 1. SOP document review revealed there was no policy and procedure to assess TP competency available at the time of the survey. 2. During an interview with TP#2 (CMS 209) on August 11, 2022 at approximately 1:15 PM in the breakroom, confirmed the lack of a written policy and procedure for all competencies as required for Hematology.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

	This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist documentation for January- December 2020, January-December 2021, and January-August 2022. 2. During an interview with the TP#1 (CMS 209) on August 11, 2022 at 12:45 PM in the breakroom, confirmed the lack of a QA checklist documentation for January-December 2020, January-December 2021, and January-August 2022.
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 laboratory document review and staff interview, the Laboratory Director (LD) failed to review and document the Testing Personnel(TP) competencies. The Findings include: 1. Competency document review revealed that the LD did not review and document TP competencies for 2020, 2021, and thus far 2022. 2. During an interview with TP#2 on August 11, 2022 at approximately 1:15 PM, in the breakroom, confirmed that the LD did not review and document TP competencies for 2020, 2021, and 2022.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on personnel records and interview with Testing Personnel(TP), the Laboratory Director failed to assess the six competency assessment criteria for testing personnel for the specialty of Hematology. The Findings include: 1. A review of testing personnel records revealed that a competency assessment was performed for laboratory procedures and skills evaluation, but the assessment did not address the six competency assessment criteria for Hematology. 2. During an interview with the TP#2

	(CMS 209) on August 11, 2022 at 1:00 PM in the breakroom, confirmed that annual competencies did not contain the six competency assessment criteria for testing personnel for the specialty of Hematology. Based on personnel records and interview with Testing Personnel(TP), the Laboratory Director failed to assess the six competency assessment criteria for testing personnel for the specialty of Hematology.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on personnel document review and staff interview, the laboratory failed to present Testing Personnel(TP) education documents. The Findings include: 1. Personnel document review revealed that the laboratory failed to present TP education documents. 2. During an interview with TP#2(CMS 209) on August 11, 2022 at approximately 12:45 PM in the breakroom, confirmed that the laboratory failed to present education documents for the TP.