Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0724969	08/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mcintosh Clinic Pc	119 West Hill St, Thomasville, 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 20, 2024. 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 (TP) competency as required. Findings include: 1. SOP review revealed there was no policy and procedure to assess (TP) competency available at the time of survey. 2. Lack of TP competency documents revealed there was no annual competencies performed for the following TP(CMS 209) TP #2 and #3. 3. An interview with TP #2 (CMS 209) on 08/20/24 at 3:20 PM in the laboratory confirmed the lack of a TP competency policy and procedure at the time of survey. During the same interview, TP #2 confirmed there were no competency documents available at the time of survey for the aforementioned staff .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing (PT) document review and interviews with the lab director (LD) and testing personnel (TP) the laboratory failed to document corrective actions of all unsatisfactory scores. Findings include: 1. Review of API PT 2023 Events 1, 2, 3 and 2024 Events 1 &2 revealed: 2023 Event 1- Total Iron received a score of 80% , 2023 Event 2 -WBC Differential received a score of 96%, 2023 Event 3-Thyroid Stimulating Hormone(TSH) received a score of 80%. No corrective actions were documented for the aforementioned PT scores. 2. An interview with the LD and TP#2 (CMS 209) in the bone density room on 8/20/24 at 4:18 p.m. confirmed the lack of corrective actions for the aforementioned PT scores.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records and interviews with the lab director (LD) and testing personnel (TP), the LD failed to ensure PT results were reviewed upon receipt from the PT agency. Findings include: 1. Review of PT result records for Hematology 2023 Event 2 revealed the LD failed to document review of PT test results. 2. Review of PT result records for Core Chemistry 2023 Event 3 revealed the LD failed to document review of PT test results. 3. Interview with the LD and TP # 2 on August 20, 2024 at 4:18 pm confirmed the aforementioned findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory records, procedure manual (SOP), and testing personnel (TP) interview, the laboratory director (LD) failed to ensure that the quality control (QC) and quality assessment (QA) programs are established and maintained to identify failures in quality. Findings include: 1. Review of the laboratory's records revealed no documentation of pre-analytic, analytic, or post-analytic monitors for the dates of November 2022 through 2024 to date. 2. No evidence of QC review by the LD on QC documents for the following analyzers: DXH 600 (hematology IQAP),

	AU480, and the Access 2 (chemistry and endochrinology) for the dates of November 2022, February 2023, August 2023, January 2024, or May 2024. 3. Interview with TP #2 on August 20, 2024 in the bone density room at 3:30 PM, confirmed the aforementioned QA and QC policy failures.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and testing personnel (TP) interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of the clinical consultant (CC), technical supervisor (TS), or the general supervisor (GS). 2. An interview with TP #2 (CMS 209) in the bone density room on 8/20/24 at 3:50 p.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure for the aforementioned positions.