

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0724969	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Mcintosh Clinic Pc	Street Address, City, State 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 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:
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview the laboratory failed to achieve satisfactory performance in the Specialty of Chemistry- Subspecialty Glycohemoglobin (A1C) , for 2/3 events in 2021. Findings: 1. Review of the API PT documents for 2021, for the Specialty Chemistry-subspecialty A1C, the laboratory received for the 1st event a score of 50%, event 2- score of 100% , event 3-a score of 0%. The laboratory did not submit specimen for event 3. 2. Interview with staff #2 (CMS 209 Personnel List) on August 11, 2022, at approximately 2:30pm in the upstairs office confirmed the aforementioned statements.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider, and staff interview the laboratory failed to document corrective action for the Specialty Chemistry-Subspecialty Glycohemoglobin (A1C) for 2021. The laboratory recieved an unsuccessful score of less than 100% for event 1 (50%) and event 3 (0%). Findings: 1. Review of the scores on the performance evaluation report for the API PT Speciality Chemistry-Subspecialty A1C, the laboratory received a score of 50% for the 1st event of 2021 and a score of 0% for the 3rd event of 2021. 2. Interview with staff #2 (CMS 209 Personnel Form) on August 11, 2022, at approximately 2pm in the upstairs office, confirmed the aforementioned statement.

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 American Proficiency Institute (API) Proficiency Testing (PT) documents, and staff interview, the Laboratory Director failed to ensure that all PT reports received are reviewed to identify any problems that require corrective action. Scores less than 100% requires the laboratory to perform and document corrective action. Findings: 1. Review of the API PT documents for the year 2021, Specialty Chemistry-Subspecialty Glycohemoglobin (A1C), the laboratory received a score of 50% for event 1 and a score of 0% for the event 3. There was no documentation of corrective action provided. 2. Interview with staff #2 (CMS 209 Personnel form), on August 11, 2022, at approximately 2pm, in the upstairs office, with the Laboratory Director, on August 11, 2022 , at appromately 3pm, in the upstairs office, confirmed that there was no documented corrective action for scores of less than 100%.