

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0724969	(X3) Date Survey Completed 06/28/2018
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 June 28, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Beckman Coulter LH500 hematology analyzer Quality Control(QC) print outs, and staff interview, the laboratory was not printing the monthly QC, including the Levey Jennings Charts, to monitor the accuracy and precision of the complete analytic process. Findings: 1. Review of the Beckman Coulter LH500 QC printouts showed that the laboratory was not printing the Monthly QC, which includes the Levey Jennings Charts to monitor the accuracy and precision of the complete analytic process. 2. Interview with staff #2 (CMS 209 form) on June 28, 2018 at approximately 2 pm, in the upstairs office, confirmed that the monthly QC reports, including the levey jennings charts were not being printed.</p>

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of the Testing Personnel (TP) training and competency documents and staff interviews, the Laboratory Director failed to meet the regulatory requirements for Competency Assessment of Testing Personnel. Findings: 1. Review of the TP competency assessment documents showed that the Yearly Employee Competency Testing consisted of a performing Proficiency Testing. The minimal six procedures for regulatory requirements for assessment of competency for all TP were not met. 2. Staff interview with the Laboratory Director, and Staff #2 (CMS form 209) on June 28, 2018 at approximately 1:50, in the upstairs office confirmed that the Competency assessment consisted of the performance of Proficiency Testing.