

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0724969	<b>(X3) Date Survey Completed</b>  11/18/2020
<b>Name of Provider or Supplier</b>  Mcintosh Clinic Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on November 18, 2020. 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:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) Proficiency Testing (PT) documents from the Third event, 2018 to the Third event, 2020, and staff interview the Laboratory Director(LD), failed to sign the Attestation Statement 19 out of 20 times. Findings: 1. Review of the APT PT documents, the Laboratory did sign the Attestation Statement for the following events.: 2020 - event 1, The LD did not sign the following Attestation Statements: Chemistry Misc. Chemistry Immunology Hematology/Coagulation 2020 - event 2, The LD did not sign the following Attestation Statements: Immunology Hematology/Coagulation 2019- event 1, The LD did not sign the following Attestation Statements Chemistry Misc Chemistry Immunology Hematology/Coagulation 2019 - event 2, The LD did not sign the following Attestation Statements Chemistry Misc. Chemistry Hematology /Coagulation 2019 - event 3, The LD did not sign the following Attestation Statements Chemistry Immunology Hematology/Coagulation 2018 - 3 event, The LD did not sign the following Attestation Statements Chemistry Immunology Hematology /Coagulation 2. Interview with staff#2, (CMS 209 form), on 11/18/2020 at approximately 4:15 pm in the Radiology Department confirmed the above aforementioned information.</p>

**D2011**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of the Beckman Coulter DxH600 Hematology Analyzer (DXH600) calibration reports, and staff interview, the laboratory failed to provide documentaion that the DXH600 was calibrated every 6 months. Findings: 1. Review of the calibration documents, the DXH600 was calibrated on 11-6-2018, and no other documented calibrations could be found. Review of the service request, did not indicate that any calibrations were performed due to service on the analyzer. 2. Interview with staff #2,(CMS 209 form), on 11/18/2020, at approximately 4 pm, in the X-ray department Bone Density room, confirmed that there was no documentation that the DXH600 had been calibrated since 11-6-2020.