

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2043142	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier Ng Medical Group, Pc	Street Address, City, State 4355 Browns Bridge Road, Suite 1 & 2, Cumming, 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 December 11, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures for assessing testing personnel (TP) competency. Findings include: 1. SOP document review revealed the laboratory failed to establish and follow written policies and procedures for performing TO competencies. 2. An interview with Staff #3 (CMS 209) in the breakroom on 12/11/18 at approximately 12:30 p.m. confirmed there were no competency policies and procedures in the laboratory SOP.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

	<p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to perform and document maintenance as defined by the manufacturer as required. Findings include: 1. Observation during the laboratory tour on 12/11/18 at approximately 11:30 a.m. revealed the Labcorp centrifuge was last calibrated on 4/9/2015. 2. An interview with the Labcorp representative in the laboratory on 12/11/18 at approximately 11:40 a.m. confirmed the Labcorp centrifuge had not be calibrated with the required frequency since 4/9/2015.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant(LD/TC) failed to provide technical oversight of the laboratory as required. Findings include: Refer to D6054</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory director/ technical consultant (LD/TC) failed to perform a six-month competency as required. Findings include: 1. TP document review revealed the TC failed to perform a 2018 six-competency for Staff #7 (CMS 209). 2. An interview with Staff #3 (CMS 209) on 12/11/18 in the breakroom at approximately 12:30 p.m. confirmed the LD/TC did not perform the aforementioned TP competency in 2018.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant (TC) failed to perform an annual competency on all TP as required. Findings include: 1. TP document review revealed the TC failed to perform an annual competency on Staff #3 (CMS 209) for 2017 and 2018 thus far. 2. An interview on 12</p>

/11/18 with Staff #3 (CMS 209) in the breakroom at approximately 12:30 p.m. confirmed the TC did not perform an annual competency for the aforementioned TP in 2017 and 2018 thus far. This is a repeat deficiency.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory failed to employ a sufficient number of individuals who meet the qualifications to perform laboratory testing as required. Findings include: Refer to D6065

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 testing personnel (TP) document review and staff interview, the laboratory failed to employ qualified TP due to lack of education documentation. Findings include: 1. TP document review revealed the laboratory failed to provide a high school diploma for Staff #7 (CMS 209) at the time of survey. 2. An interview with Staff #3 (CMS 209) in the breakroom on 12/11/18 at approximately 12:30 p.m. confirmed the aforementioned lack of education documentation. This is a repeat deficiency.