

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0899223	<b>(X3) Date Survey Completed</b>  06/22/2021
<b>Name of Provider or Supplier</b>  Next Level Medical Management, Llc	<b>Street Address, City, State</b>  1657 North Expressway, Griffin, 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 June 22, 2021. 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: A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 16, 2021. 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 review of AccuTest proficiency test (PT) records and staff interview, the lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the AccuTest PT attestation forms for 2019 event #3, 2020 event #3, and 2021 event #1 revealed the LD did not sign the attestation forms or the attestation forms were signed by an unqualified designee. 2. Interviews with staff #1 &amp; #2 (CMS 209 form) on 6/22/21 at approximately 12:00 PM in Dr. Hess' office, confirmed the aforementioned attestations were not signed by the LD or the attestation forms were signed by an unqualified designee.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual (SOP) and staff interview, the laboratory failed to follow the SOP as written and approved. Findings include: 1. SOP review reveals the laboratory is not following written procedure for testing personnel competency. The competency assessments were performed by an unqualified technical consultant (TC). 2. Competency assessment forms were pre-completed and signed by the "TC" before copies were made. 3. Interview with staff #1 (CMS 209 form) on 6/22/21 at approximately 11:45 AM in Dr. Hess' office, confirmed the TP competency was performed by unqualified staff #2 (CMS 209).

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the One World Accuracy (Accutest) proficiency test (PT) result documents, review of the Casper report 0096D, and staff interview, the laboratory failed to participate in all required hematology testing events. Findings include: 1. Review of the Accutest PT result document revealed the lab failed to participate in the 2020 test event #2 resulting in a score of 0%. 2. Review of the CMS CASPER Report 0096D revealed a score of 0% for testing event 2020 #2. 3. Interview with staff #2 (CMS 209 form) on 6/22/21 at approximately 10:30 AM in Dr. Hess' office, confirmed the laboratory failed to participate in 2020 testing event #2.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on document reviews, observations, interviews, and procedure manual review, the laboratory director failed to provide overall management and direction for multiple facets of the laboratory including: testing personnel requirements, Proficiency Testing (PT), Technical Consultant (TC), and policy & procedures. Findings include: Refer to D2009, D5209, D5215, D6004, D6029, D6032 for more details

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of personnel records and staff interview, the laboratory director (LD) failed to employ staff meeting the qualification requirements to serve as technical consultant (TC). Findings include: 1. Review of personnel records revealed the LD did not have the proper lab training or experience required to serve as TC for the moderate complexity lab. 2. Review of personnel records revealed staff #2 (CMS 209) did not have the proper education, lab training, or experience required to serve as TC for the moderate complexity lab. 3. Interviews with staff #1 & #2 (CMS 209 form) on 6/22/21 at approximately 11:45 AM in Dr. Hess' office, confirmed the lab did not employ staff to meet the education, training, or experience requirements to serve as TC.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records and staff interview, the laboratory director (LD) failed to ensure testing personnel (TP) receive the appropriate training and demonstrate competency for all testing performed to provide and report accurate results. Findings include: 1. Review of personnel records revealed staff #2 (CMS 209) did not have the proper education, lab training, or experience required to train or determine competency of TP. 2. Review of personnel records revealed staff #3 - #16 (CMS 209) did not receive training or competency reviews by staff meeting the requirement to perform the duties. 3. Interview with staff #1 (CMS 209 form) on 6/22/21 at approximately 11:45 AM in Dr. Hess' office, confirmed the TP received training and competency from unqualified staff #2 (CMS209).

**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 staff 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 each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #1 (CMS 209) in Dr. Hess' office on 6/22/21 at approximately 11:45 a.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:  
Based on review of personnel documents and interviews with the office manager and lab director, the laboratory failed to employ a qualified person to fulfill the position of Technical Consultant (TC). Findings include: Refer to D6034 for details

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:  
Based on personnel document reviews and staff interviews, the lab failed to employ a Technical Consultant (TC) who is qualified by education and either training or experience to provide technical consultation in the specialty of hematology. Findings include: 1. Review of personnel records revealed staff #2 (CMS 209) did not have the proper education, lab training, or experience required to serve as lab TC. 3. Interviews with staff #1 & #2 (CMS 209 form) on 6/22/21 at approximately 11:45 AM in Dr. Hess' office, confirmed staff #2 (CMS 209) did not meet the education, training, or experience requirements to serve as TC.