

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2205781	(X3) Date Survey Completed 08/22/2023
Name of Provider or Supplier Ncgm, Inc	Street Address, City, State 9760 Holly Springs Road, Apex, NC	
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
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's policies and procedures and review of personnel records 8/22/23, the laboratory failed to establish written policies and procedures for evaluating the competency of supervisors, and failed to perform competency evaluations for supervisory duties for 2 of 3 technical supervisors (TS #2, TS #3) and 2 of 2 general supervisors (GS #1, GS #2). Findings: Review of the "Laboratory Quality Management Plan" revealed on page 8 "... E. TECHNICAL COMPETENCE: ... The competency of all testing personnel to perform test procedures and report test results accurately and proficiently is measured periodically (twice in the first year & then annually) using a variety of techniques...". The "Laboratory Quality Management Plan" included methods used to evaluate technical skills for testing personnel, but did not describe how competency evaluations are conducted for supervisors, including the criteria for evaluation and the steps to take if the criteria are not met. Review of personnel records revealed there were no competency evaluations for technical supervisor duties for 2 of 3 technical supervisors (TS #2, TS #3). Review of personnel records also revealed there were no competency evaluations for general supervisor duties for 2 of 2 general supervisors (GS #1, GS #2).</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate</p>

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 the laboratory's policies and procedures, review of personnel records, and interview with TS (technical supervisor) #2 on 8/22/23, the laboratory director failed to ensure that prior to testing patient specimens, all personnel received appropriate training for the testing performed. Findings: Review of the "Laboratory Quality Management Plan" revealed on page 8 "... E. TECHNICAL COMPETENCE: ... Technically qualified and adequately trained personnel are essential for quality laboratory services. ... Before performing analysis, the technical competence of the personnel must be checked and practice runs performed. ... On page 32, "... 7. Personnel: ... d. Personal file/records: ... Personnel record shall include ... initial training record...". Review of personnel records revealed there were no initial training records available for 4 of 4 testing personnel (TS #2, TS #3, GS #1, GS #2). During interview at approximately 9:50 a.m., TS #2 confirmed the absence of training documentation.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory 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's policies and procedures and review of personnel records 8/22/23, the laboratory director failed to specify in writing all duties and responsibilities for 2 of 3 technical supervisors (TS #2, TS #3) and 2 of 2 general supervisors (GS #1, GS #2). Findings: Review of the "Laboratory Quality Management Plan" revealed on page 2 "... RESPONSIBILITY AND AUTHORITIES: ... The Laboratory Director is responsible for implementing the Quality Management Plan/Program (QMP).... On page 32, "... 7. Personnel: ... b. Job profile: Current job description for various key positions is available in Media Lab. ..." Review of personnel records revealed: 1. Testing personnel competency evaluations were conducted by TS #2 and TS #3, but this duty was not included in their job descriptions. 2. The job descriptions for GS #1 and GS #2 included testing personnel duties, but did not include additional general supervisor duties.