

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2290236	(X3) Date Survey Completed 12/15/2023
Name of Provider or Supplier Ngx Lawrenceville Ga Pc	Street Address, City, State 16922 Telge Rd, Suite 2c, Cypress, TX	
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	An announced survey of the laboratory was conducted on 12/15/2023. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were 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 laboratory's policies/procedures, competency assessment records and staff interview, the laboratory failed to document competency assessment for two of five laboratory personnel employed by the facility, the Technical Supervisor and General Supervisor. Findings included: 1. Review of laboratory's policy "Training and Competency Program" (approved by laboratory director on 10/30/2023) revealed: "Initial Training/Competency Each employee will be evaluated based on task lists for the individual area within the lab." The laboratory's policies did not address specific assessment of competency for Technical Supervisor, General Supervisor or Clinical Consultant. 2. Review of laboratory personnel's initial competency assessments revealed the Technical Supervisor and General Supervisor did not have documentation of competency assessment. 3. In an interview on 12/15/2023 at 1240 hours in the specimen receipt room, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 116) confirmed the findings.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the</p>

performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, personnel competency assessment records, laboratory test records and staff interview, the laboratory's Technical Supervisor failed to follow laboratory's own policy and document initial competency assessment prior to working independently for one of three testing personnel, Testing Person number 1 (TP1). Findings included: 1. Review of laboratory's policy "Training and Competency Program" (approved by laboratory director on 10/30/2023) revealed: "Once training is complete the competency assessment will be completed as the final step before the employee is allowed to work independently. And, "Competency will be assessed initially, at 6 months and annually after the first year." And, "New employees are oriented and their full competency is validated during their training period." 2. Review of the laboratory's personnel competency assessment records revealed TP1 did not have documentation of initial competency. 3. Review of laboratory's test records revealed the TP1 performed result interpretation for approximately 75,000 tests since laboratory's testing start date on November 3, 2023. 3. In an interview on 12/15/2023 at 1240 hours in the specimen receipt room, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 116) confirmed the findings.