

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2285807	<b>(X3) Date Survey Completed</b> 12/15/2023
<b>Name of Provider or Supplier</b> Ngx G Gerber Pc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures and staff interview, the laboratory failed to establish protocols for patient sample/biohazard waste disposal and personnel protective equipment (PPE) requirements for one of one test performed in the laboratory, Drug Screen and Confirmation. Findings included: 1. Review of laboratory's policies/procedures revealed that safety protocols established by the laboratory did not address patient sample/biohazard waste disposal or PPE requirements. 2. In an interview on 12/15/2023 at 1010 hours in the specimen receipt room, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 116) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid</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, consultant competency.</p>

This STANDARD is not met as evidenced by:  
 Based on review of laboratory's policies/procedures, personnel 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 07/01/2023) 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 assessment records revealed the Technical Supervisor and General Supervisor did not have documentation of competency assessment. 3. In an interview on 12/15/2023 at 1211 hours in the specimen receipt room, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 116) confirmed the findings.

**D5401**

**PROCEDURE MANUAL**  
 CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory's policies/procedures, personnel training and competency assessment documents, laboratory test records and staff interview the laboratory failed to follow its own policy and document training and initial competency assessment 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 07/01/2023) 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 training and competency assessment records revealed TP1 did not have documentation of training/initial competency. 3. Review of laboratory's test records revealed TP1 performed/interpreted results for 79,875 tests since laboratory's start date on 10/06/2023. 3. In an interview on 12/15/2023 at 1211 hours in the specimen receipt room, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 116) confirmed the findings.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
 CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor's observations and staff interview, the laboratory failed to label one of one secondary container observed in the laboratory to indicate required content identity, storage requirements, and preparation/expiration dates. Findings included: 1. Surveyor's observations in the laboratory on 12/15/2023 at 1109 hours revealed a dark bottle of unknown solution labeled only as "50/50". There was no documentation of solution component identity, storage requirements, and preparation/expiration date on the bottle. 2. In an interview on 12/15/2023 at 1109 hours in the laboratory, the facility's Testing Person number 2 (as indicated on submitted Form CMS 116) confirmed the findings.