

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2049308	(X3) Date Survey Completed 10/10/2024
Name of Provider or Supplier North Georgia Family Medicine	Street Address, City, State 4799 Blue Ridge Drive, Suite 104, Blue Ridge, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 10, 2024. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) reports and interview with the General Supervisor (GS), the laboratory failed to enroll and participate in proficiency testing (PT) for the subspecialty of urinalysis (microscopic exams). Findings: 1. Review of the 2023 & 2024 API PT reports revealed the laboratory was not enrolled/participating in PT for urine microscopic exams. 2. Interview with the GS (CMS 209) on 10/23/24 at 4:34 p.m on the phone, confirmed the aforementioned finding.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 proficiency test (PT) records and interview with the laboratory General Supervisor (GS) , the Laboratory Director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings: 1. Review of PT records for 2023 and 2024 revealed the LD did not sign the attestation statement for 10/10 PT events performed through date of the survey. 2. Interview with the GS (CMS 209), on 10/10/24, at 10 a.m, in the laboratory hall area, confirmed the finding above.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and staff interview, the laboratory failed to perform and document required QC for urine microscopic testing. Findings include: 1. Review of QC records revealed the laboratory failed to provide QC documentation for Microscopic Urinalysis 2. Interview with the General Supervisor (CMS 209), in the laboratory hall area, on 10/10/24, at 11:39 a.m., confirmed the lack of QC for aforementioned test.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the Laboratory Director (LD) failed to review PT results upon receipt from the PT agency. Findings include: 1. Review of PT records for 2023 and 2024 revealed the LD failed to review 10/10 event results upon receipt from the PT agency. 2. Interview with the General Supervisor (CMS 209), on 10/10/24, at 10 a.m, in the laboratory hall area, confirmed the finding above.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>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</p>

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 policy and procedure manual (SOP) and an interview with the General Supervisor (GS), 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. The SOP review revealed the LD failed to specify, in writing, the duties and responsibilities for the LD, Clinical Consultant (CC), and the Technical Supervisor (TS). 2. An interview with the GS (CMS 209), in laboratory hall area, on 10/10/24, at 10:39 a.m., confirmed the SOP did not contain the duties and responsibilities policy and procedure for LD, CC, or TS.

D6123

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on General Supervisor (GS) interview as well as review of quality control records (QC), maintenance records, temperature/relative humidity records, and proficiency testing (PT) records the Technical Supervisor (TS) failed to review the aforementioned documents to aid in the competency evaluations of testing personnel (TP). Findings: 1. Review of quality control records (QC), maintenance records, temperature/relative humidity records, and PT records revealed the TS was not reviewing or documenting review of the aforementioned documents. 2. Interview with the GS (CMS 209), on 10/10/24, at 10:00 a.m, in the laboratory hall area, confirmed the findings above. .

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of testing personnel (TP) competency documents and an interview with the lab General Supervisor (GS) and the office manager (OM), the Technical Supervisor (TS) failed to ensure the annual competency was performed on all testing personnel. Findings: 1. Review of the TP competency documents revealed TP # 1 (CMS 209) did not have an annual competency performed in March 2024. 2. Review

of the TP competency documents revealed TP # 2 (CMS 209) did not have an annual competency performed in May 2024. 3. Interview with the GS & OM on 10/10/24 at 09:30 a.m in the laboratory hall area, confirmed the aforementioned findings.