

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1070744	(X3) Date Survey Completed 09/14/2021
Name of Provider or Supplier Primecare Pediatrics Pc	Street Address, City, State 15a Baynard Park, Newnan, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 14, 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:
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to report SARS-CoV-2 test results to the Georgia Department of Public Health (DPH) as required. Findings include: 1. The laboratory was unable to provide documentation of disease reporting to DPH at the time of the survey. 2. Interview with the office manager on 9/14/21 in her office at 12:29 PM, confirmed the laboratory was not reporting SARS-CoV-2 test results to DPH.</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:</p>

Based on review of proficiency test (PT) records and staff interview, the laboratory testing personnel and/or lab director failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of API 2020 Event #3 PT documents revealed the testing personnel failed to attest that PT samples were tested in the same manner as patient specimens. 2. Review of API 2021 Events #1 and #2 PT documents revealed no attestation documents were available at the time of the survey. 2. An interview with the practice manager on 09/14/21 at approximately 12:40 PM in the practice manager's office, confirmed the lack of attestation documents/ signatures.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) proficiency documents and staff interview, the laboratory failed to maintain a copy of all records, including analyzer printouts, a copy of the proficiency testing program report forms, used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program. Findings include: 1. Review of API 2021 Events #1 & #2 documents revealed the lab did not maintain copies of all required documents. 2. An interview with the practice manager on 09/14/21 at approximately 12:40 PM in the practice manager's office, confirmed the lack of the required documents.

D5200

GENERAL LABORATORY SYSTEMS
CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on lack of policy and procedures for Quality Assessment and subsequent staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for each specialty and subspecialty of testing performed as required. Findings include: For details refer to D5291

<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency results and staff interview, the laboratory failed to document review of the results obtained on proficiency testing. Findings include: 1. Review of API 2020 Event #3 result documents revealed the lab did not document review of the results obtained. 2. An interview with the practice manager on 09/14/21 at approximately 12:30 PM in the practice manager's office, confirmed the lack of documented review.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) policy and procedures or documents and staff interview, the lab failed to have and follow written policies and procedures to monitor, assess, and correct problems identified. Findings include: 1. Lack of written QA policies and procedures and lack of documentation of QA monitors revealed the laboratory did not have and follow written policies and procedures to monitor, assess, and correct problems identified. 2. An interview with the practice manager on 09/14/21 at approximately 12:15 PM in the practice manager's office, confirmed the QA policies or documentation there of were not available. ** This is a repeat deficiency **</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature (RT) and humidity (RH) logs and staff interview, the laboratory failed to document RT and RH each day of testing on the Medonic M hematology analyzer. Findings include: 1. Review of RT/RH logs for August 2019 revealed the lab failed to record RH 18 of 26 days. 2. Review of RT/RH logs for March 2020 revealed the lab failed to record RH 24 of 24 days and failed to record</p>

RT 18 of 24 days. 3. Interview with the office manager on 9/14/21 in her office at approximately 12:25 PM confirmed the lack of the aforementioned missing data.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of temperature (RT) and humidity (RH) logs and staff interview, the laboratory failed to document corrective actions when the RT and RH was not documented each day of testing on the Medonic M hematology analyzer. Findings include: 1. Review of RT/RH logs for August 2019 revealed the lab failed to record RH 18 of 26 days without corective action documentation. 2. Review of RT/RH logs for March 2020 revealed the lab failed to record RH 24 of 24 days and failed to record RT 18 of 24 days without corective action documentation. 3. Interview with the office manager on 9/14/21 in her office at approximately 12:25 PM confirmed the lack of the aforementioned missing corrective actions.