

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2026934	(X3) Date Survey Completed 01/13/2022
Name of Provider or Supplier Primary Pediatrics, Pc	Street Address, City, State 164 North Lee Street, Forsyth, 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 January 13, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following Condition and Standard Level citations were cited:
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 the American Proficiency Institute (API), Proficiency Testing (PT) documents, and staff interview, the laboratory failed to provide a signed Attestation Statement for the PT documents in 2020, and 2021. Findings: 1. Review of the PT documents for 2020, the laboratory did not have signed attestation statement for: Specialty- Chemistry, event 1 or 2 Specialty- Hematology, event 1, 2, or 3 Specialty- Microbiology, event 1, 2, and 3 2. Review of the PT document for 2021, the laboratory did not have signed attestation statements for: Specialty-Chemistry, event 1 Specialty-Hematology, event 1 and 3 Specialty-Microbiology, event 1, 2, and 3 3. Staff interview with the laboratory manager ,on January 13, 2022, at approximately 1:35 pm in the office/storage room, Confirmed the above aforementioned statements.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I</p>

of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:
Based on review of the American Proficiency Institute (API), Proficiency Testing (PT) provider documents, and staff interview the laboratory failed to successfully participate in PT for the year 2020, and 2021. Reference: D2028, D2131,

D2028

BACTERIOLOGY
CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the laboratory failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events in Microbiology. Findings: 1. PT documents from 2020, for Microbiology, the laboratory scored 50% for event 1, and 50% for event 2. 2. Staff interview with the laboratory manager on January 13, 2022, at approximately 1:40 pm in the office/storage room, confirmed the aforementioned statement.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents, and staff interview, the laboratory failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events for Hematology, subspecialty Erythrocyte Sedimentation Rate (ESR). Findings: 1. Review of the PT documents for 2020, speciality Hematology, sub-specialty ESR, the laboratory received a score of 50% for event 1, and a score of 0% for event 2. 2.

	<p>Review of the PT documents for 2021, speciality Hematology, sub-specialty ESR, the laboratory received a score of 0% for event 1 and a score of 50% for event 2. 3. Staff interview with the laboratory manager, on January 13, 2022, at approximately 1:45 pm, in the office/storage room, confirmed the aforementioned statements.</p>
<p>D5439</p>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of the calibration documents for the Cell Dyn Emerald (Emerald), and staff interview, the laboratory failed to perform calibration every six months. Findings: 1. Review of the calibration documents, the laboratory performed calibration on the Emerald the following dates: 09/14/2021 and 05/17/2021. There was no documentation of calibrations in 2020. 2. Interview with the Lab Manager, on January 13, 2022 at approximately 1:30 pm in the office/storage room, confirmed the aforementioned documentation.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute, (API) Proficiency Testing (PT) Provider, the Laboratory Director failed to provide overall management and direction. This is a Condition Level Citation. Reference: D6018, D200</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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;

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) sample provider, and staff interview, the Laboratory Director(LD) failed to provide documentation of review of the APT PT evaluation reports in 2020 and 2021.

Findings: 1. Review of the API, PT evaluation reports for 2020, the LD did not sign the evaluation reports documenting review for the following: Speciality Chemistry, sub-speciality: Lead, and Total Bilirubin for events 1, 2, and 3. Speciality Hematology, Complete Blood Count: events 1, 2, and 3. Speciality Microbiology, Throat and Urine cultures: event 1, 2, and 3. 2. Review of the API, PT evaluation reports for 2021, the LD did not sign the evaluation reports documenting review for the following : Speciality Chemistry, sub-speciality: Lead, and Total Bilirubin for events 1, 2, and 3 Speciality Hematology, Complete Blood Count: events 2 and 3 Speciality Microbiology, Throat and Urine cultures: events 1, 2, and 3. 3. Interview with the lab manager, on January 13, 2022, at approximately 2:00 pm, in the office /storage room, confirmed the above aforementioned statements.