

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0968730	(X3) Date Survey Completed 05/30/2023
Name of Provider or Supplier Princeton Pediatrics	Street Address, City, State 104 Commercial Drive, Princeton, NC	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the CMS-209 Laboratory Personnel Report, review of 2021, 2022, and 2023 CAP (College of American Pathologists), MLE (Medical Laboratory Evaluation), and AAB (American Association of Bioanalysts) proficiency testing records and interview with the clinical supervisor 5/30/23, the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested. Findings: 1. Review of "THE QUALITY ASSURANCE PLAN" revealed "... Proficiency testing / Competency testing are done by all providers twice a year. ..." Review of the CMS-209 Laboratory Personnel Report signed by the laboratory director 5/23/23 revealed the laboratory employs 5 physicians, 3 nurse practitioners, and 1 physician assistant who perform laboratory testing. Review of 2021, 2022, and 2023 CAP proficiency testing records revealed that only 3 of the physicians (TP #1, TP #3, TP #5) had participated in proficiency testing. There was no documentation available to indicate that any of the other providers had participated in proficiency testing. During interview at approximately 2:20 p.m., the clinical manager stated they didn't realize the nurse practitioners and physician assistant needed to participate. 2. Review of the laboratory's policies and procedures revealed a list of panic values for the laboratory.</p>

The list included panic values for hemoglobin, WBC (white blood cell count), platelet count, and hematocrit. Review of 2021 and 2022 MLE and 2023 AAB proficiency testing records revealed no documentation that panic values were repeated. Examples: a. 2021 MLE M1 - samples HD-2 and HD-4 had panic values for WBC with no documentation they were repeated. b. 2022 MLE M2 - samples HD-6 and HD-10 had panic values for WBC and hemoglobin with no documentation they were repeated. c. 2023 AAB nonchemistry M1 - samples HD-2 and HD-5 had panic values for WBC, hemoglobin, and platelet count with no documentation they were repeated. During interview at approximately 2:30 p.m., the clinical supervisor stated that panic values obtained on patient specimens are repeated to verify prior to reporting. She stated panic values obtained on proficiency samples are also repeated but they didn't realize they needed to save the printouts for the repeats.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures and review of A disc (bacitracin) quality control records 5/30/23, the laboratory's A disc quality control records failed to include the date that quality control results were read. Review of the laboratory's "ADISC QUALITY CONTROL" procedure states "... 3. The plate is incubated at 34-36 C for 24 hours. 4. Results are read by the Physicians the following morning. ..." The procedure did not include instructions for documenting the date that plates were read. Review of 2021, 2022, and 2023 A disc quality control records revealed the A disc quality control logs included a column for the date quality control organisms were plated, but did not include a column for the date the plates were read.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

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 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 personnel records and interview with the clinical supervisor 5/30 /23, the laboratory director failed to specify in writing the duties for the clinical consultant and the technical consultant. Review of personnel records revealed there were no job descriptions (list of duties and responsibilities) available for the clinical

consultant and the technical consultant. During interview at approximately 11:00 a.m. the clinical supervisor confirmed there were no job descriptions available for the clinical consultant and the technical consultant.