

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0686947	(X3) Date Survey Completed 05/04/2022
Name of Provider or Supplier Piedmont Pediatrics	Street Address, City, State 105 Collier Road Suite 4060, Atlanta, 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 May 4, 2022. Condition and Standard level citations were found. 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:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents, and staff interview the laboratory failed to enroll in Proficiency Testing for the year 2020 events A, B,C and 2021 events A,B, for the Speciality of Microbiology, subspecialty Throat Culture. Reference: D2020</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 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</p>

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 College of American Pathologist (CAP) Proficiency Testing (PT) documents, 096 Casper Report and staff interview the laboratory failed to enroll in Proficiency Testing for the year 2020 events A, B,C and 2021 events A,B, for the Speciality of Microbiology, subspecialty Throat Culture. Reference D2020

D2020

BACTERIOLOGY
CFR(s): 493.823(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents, 096 Casper Report and staff interview the laboratory failed to enroll in Proficiency Testing for the year 2020 events A, B,C and 2021 events A,B, for the Speciality of Microbiology, subspecialty Throat Culture. Failure to enroll in PT for the speciality Microbiology, subspecialty Throat Culture is equivalent to unsatisfactory performance for those events that PT was not performed. Findings: 1. Based on document review and the 096 Casper Report, the laboratory failed to enroll in and participate in PT for the year 2020, events, A, B, C, and the year 2021 events, A and B. Non participation resulted in three unsuccessful scores out of five. 2. Interview with Clinical Nurse Manger on May 4, 2022, at approximately 1:30 pm, in the office confirmed that the aforementioned statement.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on review of the College of American Pathologist (CAP), Proficiency Testing (PT) provider and staff interview, the Laboratory Director failed to provide overall management and direction in making sure the Laboratory had ordered and participated in the CAP PT proficiency testing for the Special of Microbiology, and subspecialty

of Throat Culture for the three events in 2020, and two out of three events, in 2021.
Reference: D6015

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) Proficiency Testing (PT) documents, 096 Casper Report and staff interview the laboratory failed to verify that the laboratory was enrolled in Proficiency Testing for the year 2020 events A, B, C and 2021 events A,B, for the Speciality of Microbiology, subspecialty Throat Culture. Findings: 1. Review of the CAP PT documents and the 096 Casper report showed that the laboratory was not enrolled with a PT provider for the speciality Microbiology, sub specialty Throat Culture for the year 2020 events A, B, C and 2021 events A and B. 2. Staff interview with the Clinical Nurse Manager, on May 4, 2020, at approximately 1:45 pm, in the office, confirmed the aforementioned statement.