

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0903572	(X3) Date Survey Completed 06/21/2022
Name of Provider or Supplier Preston Ridge Pediatric Assoc Pc	Street Address, City, State 3400-A Old Milton Pkwy Ste 330, Alpharetta, 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 June 21, 2022. 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:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly or quarterly basis per their QA guidelines as required. The Findings include: 1. Laboratory QA document review revealed the laboratory had an annual QA checklist instead of monthly or quarterly in 2020 thru 2022. 2. No evidence of a problem log for failed QC or any other problems arising in the lab during testing. 3. No evidence of maintenance, refrigerator or room temperature logs reviewed on a regular basis in 2020 thru 2022. 3. An interview with the Laboratory Director, on 06/21/2022, at 12: 15 PM, in the review room, confirmed the lack of adequate QA checklist and problem logs for the laboratory in 2020 thru 2022.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on Quality Control (QC), Quality Assurance (QA) document review and staff interview, the Lab Director (LD) failed to ensure that proper QA guidelines were followed including regular review of instrument Quality Control (QC) data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. (QC) and (QA) document review revealed the laboratory director did not review daily urinalysis (QC) instrument data, throat culture control logs or implement a QC monitoring program to identify and correct problems in the laboratory as required in 2020 thru 2022. 2. An interview with the Laboratory Director, in the review room, on 06/21/2022, at approximately 12:50 PM, confirmed the LD did not review the aforementioned (QC) data in 2020 thru 2022.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the Laboratory Director, the laboratory did not have a competency assessment policy that met the Clinical Laboratory Improvement Amendment (CLIA) six standards Criteria for testing personnel. Findings include: 1. Testing Personnel (TP) record review revealed that competency assessment was performed in 2020 and 2021; however, the assessment did not contain the six CLIA standard criteria for personnel competency assessments. 2. An interview with the Laboratory Director, on 06/21/2022, at approximately 12:33 PM, in the review room, confirmed the laboratory competency assessment policy does not contain the CLIA competency six standard criteria for years 2021 and 2022.