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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 11D0903572 | (X3) Date Survey Completed 01/16/2020 |
| 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 |
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| D0000 | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 16, 2020. 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: |
| D2015 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Association of Bioanalysts PT document review revealed attestation statements were unavailable at the time of survey for the following Bacteriology PT events: 2018 - Event Three and 2019 - Event One. 2. An interview with the laboratory director /technical consultant (LD/TC) in a doctor's office on 1/16/2020 at approximately 1:30 p.m. confirmed the lack of attestation statements for the aforementioned PT events.</p> |
| D6004 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to delegate the performance of TP competencies to qualified TP as required. Findings include: 1. TP competency document review revealed all TP competencies for Staff #2 through Staff #8 (CMS 209) for 2018 and 2019 were performed by unqualified TP due to lack of education qualifications. 2. An interview with the LD/TC in a doctor's office on 1/16/2020 at approximately 1:00 p.m. confirmed the aforementioned competencies were performed by unqualified TP.