Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 42D0250784	**(X3) Date Survey Completed** 11/07/2024
Name of Provider or Supplier Parkwood Pediatric Group	**Street Address, City, State** 1483 Tobias Gadson Blvd, Suite 109, Charleston, SC	
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	An announced onsite CLIA recertification survey was conducted on November 7, 2024, at the clinical laboratory of Parkwood Pediatrics Group in Charleston by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of Condition and Standard level deficiencies cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) documentation, and staff interview, the laboratory director (LD) and testing personnel (TP) failed to document on the attestation sheet that proficiency test (PT) specimens were testing the same manner as patient specimens. Findings included: 1. Review of API Attestation Sheet for 1st event Microbiology of 2023 reveals that the form was not signed by the LD or TP for that event. 2. Review of API PT documentation reveals a lack of evidence of review in 1 of 18 attestation sheets in 2023. 3. In an interview on November 7, 2024, at 12:15pm with TP1 in the laboratory office, the findings were confirmed.

D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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 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 API performance summary for urinalysis for 2023, the laboratory failed to successfully participate in a CMS approved proficiency testing program. Findings included: 1. Review of API PT test scores reveal the following: a. Urinalysis pH score of 0% for the first event of 2023 b. Urinalysis pH score of 0% for the second event of 2023 2. Review of API PT test scores reveals unsuccessful participation in a CMS approved PT program in two consecutive events in 2023. 3. In an interview on November 7, 2024, at 12:15pm with TP1 in the laboratory office, the findings were confirmed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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 API PT test scores for 2023, lack of laboratory documentation, and staff interview, the LD failed to ensure all PT reports are reviewed to evaluate the laboratory's performance and identify any problems that require corrective action. Findings included: 1. Review of API Attestation Sheet for 1st event Microbiology of 2023 reveals that the form was not signed by the LD or TP for that event. 2. Review of API PT documentation reveals a lack of evidence of review in 1 of 18 attestation sheets in 2023. 3. In an interview on November 7, 2024, at 12:15pm with TP1 in the laboratory office, the findings were confirmed