

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0664387	(X3) Date Survey Completed 11/22/2024
Name of Provider or Supplier Pediatric Care Center,The	Street Address, City, State 5612 Spruce Tree Ave, Bethesda, MD	
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
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <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. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the duties and responsibilities of the laboratory staff and interview with the testing person (TP) and laboratory director (LD), the LD did not ensure that the duties and responsibilities of the TP and technical consultant (TC) included instructions for the evaluation of laboratory quality control (QC) and quality assessment (QA) documentation to assure the quality of the laboratory services. Findings: During the survey on 11/22/24 at 12:45 PM, the TP and LD confirmed that duties and responsibilities did not include written instructions for the TP to submit QC and QA records at the beginning of the next month to the TC for review. The duties and responsibilities did not include written instructions for the TC to receive, evaluate, and submit follow up information to the TP and LD.</p>