Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2059207	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Pediatric Specialists Of Tulsa	**Street Address, City, State** 7412 S Yale, Tulsa, OK	
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	The recertification survey was performed on 05/21/2025. The laboratory was found out of compliance with the following CLIA Condition: 493.1421; D6063: Laboratories performing moderate complexity testing; testing personnel The findings were reviewed with the office manager and testing person #1 during an exit conference performed at the conclusion of the survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the office manager and testing person #1, the laboratory failed to ensure written policies and procedures had been approved, signed, and dated by the laboratory director. Findings include: (1) On 05/21/2025 at 09:00 am, the office manager and testing person #1 stated the laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DXH 520; (2) A review of the manual titled, "CLIA Compliance Manual DxH 520 Analyzer Policies and Procedures" identified no evidence the manual had been signed and dated as approved by the laboratory director; (3) The findings were reviewed with the office manager and testing person #1. Both stated on 05/21/2025 at 01:55 pm, the manual contained the policies and procedures and had not been signed and dated by the laboratory director.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.

	1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with the office manager, the laboratory failed to ensure individuals who performed moderate complexity testing met the educational qualifications for one of three persons listed on the Form CMS-209. Findings include: (1) The laboratory failed to ensure a testing person met the educational qualifications. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of records and interview with the office manager, the laboratory failed to ensure a testing person met the educational qualifications to perform moderate complexity testing for one of three testing persons listed on the Form CMS-209. Findings include: (1) On 05/21/2025 at 09:00 am, the office manager and testing person #1 stated the laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DXH 520 analyzer; (2) A review of personnel records for testing person #3 revealed no evidence of an education document to ensure the individual met the moderate complexity personnel requirements; (3) The findings were reviewed with the office manager who stated on 05/21/2025 at 11:00 am, the education document was not available.