

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2059207	(X3) Date Survey Completed 07/06/2021
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 07/06/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the office manager, testing person #1, and testing person #2 at the conclusion of the survey.
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 a review of records and interview with the office manager, the laboratory failed to ensure an attestation statement had been signed by the laboratory director or designee for 1 of 6 events. Findings include: (1) The surveyor reviewed 2019 (second and third events), 2020 (first, second, and third events) and 2021 (first event) Hematology proficiency testing records with the following identified: (a) Third 2020 Hematology Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor reviewed the records with the office manager, who stated on 07/06/2021 at 1:05 pm, the attestation statement had not been signed by the laboratory director or designee.</p>

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(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 07/06/2021 at 10:30 am, testing person #1 stated to the surveyor the Beckman Coulter DxH analyzer was put into use to perform patient CBC (Complete Blood Count) testing on 04/24/2020; (2) The survey reviewed the manual titled, "CLIA Compliance Manual DxH Analyzer Policies and Procedures", which contained written policies and procedures. There was no indication the manual had been approved, signed, and dated by the laboratory director; (3) The surveyor showed the manual to the office manager and testing person #1. Both stated on 07/06/2021 at 01:30 pm, the manual contained the policies and procedures and had not been signed and dated by the laboratory director.