Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1021787	**(X3) Date Survey Completed** 06/25/2024
Name of Provider or Supplier Texas Childrens Pediatrics Lakewood	**Street Address, City, State** 13215 Grant Road, Suite 100, Cypress, TX	
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	Based on a validation survey performed on June 25, 2024, the laboratory found in compliance with 42 CFR Part 493, Requirements for Laboratories. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy, the CMS 209 form, the laboratory's API proficiency testing attestation sheets in 2023, and confirmed in an interview, the laboratory failed to ensure that proficiency testing samples were analyzed by personnel who routinely performed patient testing in the laboratory for 3 of 3 proficiency testing events. The findings were: 1. Review of the laboratory's policy titled Laboratory Quality Assurance TCP/TCUC Policy (2315) under 4. Proficiency Testing/Split Sampling revealed "4.7 All laboratory testing personnel will participate in performing the testing program using routine test methods." 2. Review of the CMS 209 Laboratory Personnel Report (CLIA), signed by the laboratory director on 06/27 /2024, revealed 5 testing personnel performing moderate complexity testing. 3. Review of the API proficiency testing attestation sheets in 2023 revealed all samples were tested by Testing person #1 for 3 of 3 proficiency testing events. 2023 Chemistry Core 1st Event Sample: NB-01 to NB-05 2023 Chemistry Core 2nd Event Sample: NB-06 to NB-10 2023 Chemistry Core 3rd Event Sample: NB-11 to NB-15 3. In an interview on 06/25/2024 at 2:00 pm in the break room, the laboratory supervisor confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services API=American Proficiency Institute NB=Bilirubin, Total (neonatal) (mg/dL)