Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0952507	05/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
University Pediatrics	615 East University Drive, Edinburg, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, review of the laboratory's proficiency testing records from 2022 and 2023, and staff interview it was revealed the laboratory failed to have documentation of 1 of 2 testing personnel participating in proficiency testing in 2022 and 2023. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 2 testing personnel. 2. A review of the laboratory's personnel records revealed: Testing personnel number 1 was employed starting in 2014. Testing personnel number 2 was employed starting in 2017. 3. A review of the laboratory's American Academy of Family Physician's (AAFP) proficiency testing records from 2022 (A, B and C) and the laboratory's Wisconsin State Laboratory of Hygiene proficiency testing records from 2023 (event 1) revealed all testing was performed by testing personnel number 1 (as listed on Form CMS 209). 4. The laboratory was asked to provide documentation of testing personnel number 2 participating in proficiency testing. No documentation was provided. 5. An interview with the technical consultant on 05/03/2022 at 920 hours in the break room - after her review of the records- confirmed the findings.
D3031	RETENTION REQUIREMENTS

	CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's new lot verification records from 2022 and 2023, it was revealed the laboratory failed to retain the the records for the verification of new lots of Boule Condiff - Trilevel quality control for 5 lots in 2022. The findings include: 1. A review of the laboratory's quality control records from 2022 revealed the laboratory failed to retain documentation of performing new lot verifications for the following lots of quality control material: Lot: 22110 Lot: 22111 Lot: 22202 Lot: 22205 Lot: 22206 2. The laboratory was asked to provide the missing documentation. No documentation was provided. 3. An interview with the technical consultant on 05 /03/2023 at 1015 hours in the break room revealed the was unable to locate the records. This confirmed the findings.