Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1102217	09/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center Of Southwest Louisiana, The	2800 Country Club Road, Lake Charles, LA	

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	A Certification Survey was performed on September 17, 2019 at The Pediatric Center of Southwest Louisiana, CLIA ID # 19D1102217. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation statement for four (4) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Academy of Family Physicians (AAFP) proficiency records for 2018 and 2019 revealed the Laboratory Director did not sign the attestation statement for the following events: a) AAFP-PT 2018-A b) AAFP-PT 2018-B c) AAFP-PT 2019-A d) AAFP-PT 2019-B 2. In interview on September 17, 2019 at 10:06 am, Personnel 2 stated that each laboratory under the Pediatric Associates has its own Medical Technologist supervision and that supervisor is responsible for obtaining all signatures on the attestation statements. Personnel 2 further stated that the supervisor for this laboratory is no longer employed. 3. In further interview, Personnel 2 confirmed the Laboratory Director did not sign the attestation statement for the above events.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons

	other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for an unacceptable proficiency test (PT) results for 2018 and 2019. Findings: 1. Review of the laboratory's 2018 and 2019 American Academy of Family Physicians (AAFP) PT results revealed the laboratory received the following unacceptable results: a) AAFP-PT 2018-A: Sample HD-3 for Mean Corpuscular Volume (MCV) b) AAFP-PT 2019-B: Sample HCT for Hematocrit (HCT) 3. In interview on September 17, 2019 at 10:06 am, Personnel 2 confirmed the laboratory did not perform corrective action on unacceptable results for the above events.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2009.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D2128.