Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0701010	10/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pearland Pediatrics Pa	2017 East Broadway Suite A, Pearland, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control records and error logs, patient reports, and confirmed in interview, the laboratory failed to document corrective action when quality control for CBC (complete blood count) testing were outside of the acceptable range for the Medonic M-series hematology analyzer. Findings were: 1. Random sampling review of the CBC Log from January 2019 to September 2019 revealed 5 of 20 days when the quality control was unacceptable with no documentation of correction action. 2/1/19 control lot 2181121 2/28/19 control lot 2181121 3/20/19 control lot 2181122 4/5/19 control lot 2190221 5/29/19 control lot 2190223 2. Random review of patient test records revealed the laboratory performed

	patient testing for the above dates. 2/1/19 Patient ID: 34497 2/28/19 patient ID: EV010712 3/20/19 patient ID: 143242. 46543, 46305 4/05/19 patient ID: 46656, 46921 5/29/19 patient ID: 44738 3. Interview with the technical consultant on 10/8/19 at 1100 hours in the conference room confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of quality assessment reports and interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5781