

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0701010	(X3) Date Survey Completed 04/21/2023
Name of Provider or Supplier Pearland Pediatrics Pa	Street Address, City, State 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 was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the manufacturer's CDS/Medonic M-series maintenance, the laboratory's records in 2022, CMS 116 application and confirmed in an interview, the laboratory failed to have documentation of required maintenance on Medonic M-series hematology analyzer for 12 of 12 months in 2022 The findings were: 1. Review of the manufacturer's CDS/Medonic M-Series Maintenance (207054B 03.19.12) revealed the required maintenance as follows: Daily Maintenance Monthly cleaning procedures Six month cleaning procedures 2. Review of the laboratory's records in 2022 revealed the laboratory did not have documentation of required maintenance on Medonic M-series hematology analyzer (SN: 24071) for 12 of 12 months in 2022. 3. Review of the CMS 116 application signed by the laboratory director on 4/18/2023 revealed the hematology annual volume was 1905. 4. An interview with the technical consultant and a LVN on 4/21/2023 at 11:39 am in the conference room confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services</p>