Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2147425	10/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Pediatric Clinic	16115 St Vincent Way, Ste 320, Little Rock, AR	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based upon review of Medonic M-Series Hematology Analyzer Checklist, lack of documentation and interviews with laboratory staff, the laboratory failed to perform maintenance on the Medonic M-Series Hematology Analyzer in 2024 and 2025 Survey findings include: A) The Medonic M-Series Maintenance Checklist (User Manual, Section 6.1 and 8.1) includes a required daily "Clean Probes With Alcohol" the Medonic M-Series Maintenance Checklist (User Manual, Section 8.1) includes required monthly maintenance "monthly cleaning (hypochlorite). B) Upon request, the laboratory was unable to provide documentation of routine maintenance performance for the Medonic M-Series Hematology analyzer for the 2024 and 2025 calendar years. C) In an interview, at 11:40 a.m. on 10/7/25, laboratory staff member #4 (as listed on the form CMS-209) stated that the Medonic M-Series Hematology Analyzer was placed into use in 2017, and confirmed that Daily and Monthly required maintenance was not documented.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: Based upon a review of the the laboratory's "Quality Control Protocol", Complete Blood Cell Count (CBC) All Sample Summary report for July 2025, lack of documentation, and interviews with laboratory staff, the laboratory failed to document corrective actions when results of control materials failed to meet the laboratory's established criteria for acceptability on 15 of 24 days of operation. Survey findings follow: A) The laboratory Quality Control (QC) Protocol states that after an unsuccesful QC result is repeated, "if the repeated result is still outside of the expected range, documented corrective action should be initiated". B) Review of the All Sample Summary Report for July 2025 for Con Boule Diff QC controls lot # 22503 level 1, level 2, level 3 revealed: * on 7/1/25 level 1 was repeated 2 times, level 2 was repeated 3 times, and level 3 was repeated 4 times before QC results met the laboratory's criteria for acceptance. * on 7/2/25 level 1 was repeated 4 times, level 2 was repeated 5 times, and level 3 was repeated 6 times before QC results met the laboratory's criteria for acceptance. * on 7/3/25 level 1 was repeated 2 times, level 2 was repeated 3 times, and level 3 was repeated 4 times before QC results met the laboratory's criteria for acceptance. * on 7/7/25 level 1 was repeated 2 times, and level 3 was repeated 3 times before QC results met the laboratory's criteria for acceptance. * on 7/8/25 level 3 was repeated 2 times before QC results met the laboratory's criteria for acceptance * on 7/9/25 level 3 was repeated 2 times before QC results met the laboratory's criteria for acceptance. * on 7/10/25 level 1 was repeated 2 times, level 2 was repeated 2 times before QC results met the laboratory's criteria for acceptance. * on 7/11/25 level 1 was repeated 2 times, level 2 was repeated 4 times, and level 3 was repeated 2 times before QC results met the laboratory's criteria for acceptance. * on 7 /18/25 level 1 was repeated 2 times, and level 3 was repeated 2 times before QC results met the laboratory's criteria for acceptance. * on 7/22/25 level 1 was repeated 4 times, level 2 was repeated 4 times, and level 3 was repeated 4 times before QC results met the laboratory's criteria for acceptance. * on 7/24/25 level 1 was repeated 3 times, an level 2 was repeated 2 times,before QC results met the laboratory's criteria for acceptance. * on 7/28/25 level 2 was repeated 5 times, and level 3 was repeated 5 times before QC results met the laboratory's criteria for acceptance. * on 7/30/25 level 1 was repeated 2 times, level 2 was repeated 2 times, and level 3 was repeated 4 times before QC results met the laboratory's criteria for acceptance. * on 7/31/25 level 1 was repeated 2 times, level 2 was repeated 2 times, and level 3 was repeated 2 times before QC results met the laboratory's criteria for acceptance. C) Upon request, the laboratory was unable to provide documentation of the corrective action taken to achieve acceptable QC results in the events identified above. D) In an interview at 10: 07 on 10/7/25, the laqboratory staff member (#4 on the form CMS-209) confirmed that no corrective actions were documented for events listed above.