

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2270201	<b>(X3) Date Survey Completed</b>  11/08/2024
<b>Name of Provider or Supplier</b>  Kion Pediatrics	<b>Street Address, City, State</b>  11 Southpointe Drive, Suite K, Paragould, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Review of the laboratory's policy and procedure for hematology quality control (QC), acceptable range sheets for CDS Boule Con-Diff Multi-Parameter Assayed Hematology Controls, All Data Summary Reports provided by the Medonic M-Series analyzer, maintenance checklist for the Medonic M-Series Hematology Analyzer, lack of documentation and interview with laboratory staff determined the laboratory testing failed to meet the applicable analytic systems requirements as evidenced by: D5429: The laboratory failed to document and/or perform maintenance required for the proper operation of the Medonic M-Series Hematology Analyzer. D5445: The laboratory failed to perform daily QC prior to releasing patient results on July 23, 2024. D5783: The laboratory failed to document corrective action taken to achieve acceptable QC results on five of five occasions when QC results were unacceptable and repeated QC analysis was required to achieve acceptable results.</p>
<b>D5429</b>	<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>

This STANDARD is not met as evidenced by:  
 Review of review of Medonic M-Series Hematology Analyzer Checklist for July 2024 through October 2024 and interviews with laboratory staff, determined the laboratory failed to perform monthly maintenance on the Medonic M-Series Hematology Analyzer in four of four months reviewed. 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) The daily "Clean ProbesWith Alcohol" and the monthly "Monthly Cleaning (hypochlorite)" was not documented in July, August September, And October. C) The Medonic M-Series Maintenance Checklist had no documentation of performance of Daily required maintenance or Monthly required maintenance for the months reviewed D) In an interview, at 10:55 a.m. on 11/8/24, laboratory employee #3 (as listed on the form CMS-209) stated that the Medonic M-Series Hematology Analyzer was placed into use in July 2024 and confirmed that Daily and Monthly required maintenance was not documented.

**D5445**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
 (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
 Review of the laboratory's "Quality Control (QC) Protocol", complete blood cell count (CBC) data logs, lack of documentation and interview determined that the laboratory reported patient CBC result without performing required quality control on one of one days of operation in July 2024. Findings follow: A) Review of the laboratory's "Quality Control Protocol" revealed that "Hematology (low, normal, high) are performed on each day of patient testing and "if three levels are run (Hematology), at least two levels must be within established acceptable range before reporting patient results". B) Review of CBC data log revealed that a CBC was performed and reported on patient 07082023 on Tuesday, 7/23/24 with no evidence of quality control being performed on that day. C) In an interview on 11/8/24 at 10:15 a. m. the laboratory staff member (identified as number 3 on form CMS 209) confirmed that a CBC was run and reported on that day without the required quality control being performed and the complete instrument validation had not been completed until 7/25/24.

**D5783**

**CORRECTIVE ACTIONS**  
 CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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:

Review of the laboratory's "Quality Control Protocol, the Medonic Hematology analyzer "all data summary" report for July 2024, and October 2024, lack of documentation, and interview with laboratory staff determined that the laboratory failed to document corrective action on five of five occasions in July 2024 and October 2024 when quality control results failed to meet the laboratory's defined criteria for acceptability. Findings follow: A) Review of the laboratory's Quality Control Protocol revealed that when control performance is unacceptable, "controls should be repeated, if the repeated result is still outside of the expected range documented corrective action should be initiated". . B) Review of the Medonic all data summary report revealed that on 7/31/24 Red Blood Cell Count (RBC) low control lot# 2240401 with an acceptable range of 2.12 to 2.36 was resulted as 2.11, at 1659 hours before being acceptable as 2.36 at 1702 hours, RBC normal control with an acceptable range of 3.93 to 4.31 was resulted as 4.56 at 1700 hours and 4.37 at 17.03 hours without subsequent attempts recorded within acceptable range. C) Upon request, the laboratory was unable to provide documentation of the corrective action taken for the event identified above. D) Review of the Medonic all data summary report revealed that on 10/08/24 RBC high control lot# 2240303 with an acceptable range of 4.88 to 5.32 was resulted as 5.67 at 0802. and no result within acceptable range was recorded subsequently, low control lot# 2240301 with an acceptable range of 2.12 to 2.36 was reesulted as 2.42 at 0748 before being reported within acceptable range as 2.36 at 0809. E) Upon request, the laboratory was not able to provide documentation of corrective action required to achieve acceptable QC results for the event identified above. F) Review of the Medonic all data summary report revealed that on 10/14/24 RBC normal control lot# 2240302 with an acceptable range of 3.98 to 4.34 was resulted as 2.44 and 3.42, between 0743 and 0748 before resulting within acceptable range of 4.11 at 1017 and RBC high control lot# 2240303 with an acceptable range of 4.88 to 5.32 was resulted as 4.08 and 4.47 between 1014 and 1017 and no result within acceptable range was recorded. G) Upon request, the laboratory was not able to provide documentation of corrective action required to achieve acceptable QC results for the event identified above. H) Review of the Medonic all data summary report revealed that on 7/10/24 Hemoglobin (Hgb) high control lot# 2240303 with an acceptable range of 15.7 to 16.7 was recorded at 17.1 and 17.4 between 0744 and 1000 with no acceptable result attained. I) Upon request, the laboratory was not able to provide documentation of corrective action required to achieve acceptable QC results for the event identified above. J) In an interview on 11/8 /24 at 09:15 a.m., the laboratory staff member (number 3 on form CMS 209), when asked if the corrective action was documented for the instances identified above, stated "probably not".