

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2167266	(X3) Date Survey Completed 11/07/2024
Name of Provider or Supplier Kion Pediatrics	Street Address, City, State 3410 E Johnson Ave Suite T, Jonesboro, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Observation, review of temperature records, lack of documentation and interview demonstrated that the laboratory failed to monitor the temperature on each day of operation in one of two rooms in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 11/7/24 at 12:34 p.m., the surveyor observed two rooms (laboratory and office/storage) containing laboratory items with a temperature storage requirement. B) A review of the laboratory's temperature records revealed that no room temperatures were recorded for the office/storage room for the period of April 2024 to the date of the survey. C) During a tour of the laboratory on 11/7/24 at 02:15 p.m. the surveyor observed 2 boxes of Medonic M-Series Pack with a storage temperature requirement of 4 degrees to 35 degrees Centigrade (C) lot # 2408-006, expiration date 2027-03-31, in the office/storage room. D) Upon request, the laboratory could not present the temperature records for the office/storage room in which the supplies identified above were stored. E) In an interview on 11/7/24 at 02:35 p.m., the laboratory staff member (# 4 on form CMS 209) confirmed that temperature records for the office/storage room were not recorded.</p>
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, lack of documentation, and interview with laboratory staff determined that the laboratory failed to document corrective action on two of two occasions in July 2024 when Red Blood Cell Count (RBC) 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 7/01/24 RBC normal control lot# 2240302 with an acceptable range of 3.98 to 4.34 was resulted as 4.47, 4.61, 4.55, between 07:43 a.m. and 08:22 a.m. before resulting within acceptable range of 4.24 at 08:26 a.m.. C) Review of the Medonic all data summary report revealed that on 7/01/24 RBC high control lot# 2240303 with an acceptable range of 4.90 to 5.34 was resulted as 5.43, 5.45, 5.79, 5.51 between 07:40 a.m. and 08:12 a.m. before resulting within acceptable range of 5.25 at 08:15 a.m.. D) Review of the Medonic all data summary report revealed that on 7/10/24 RBC normal control lot# 2240302 with an acceptable range of 3.98 to 4.34 was resulted as 4.36, 4.43, between 07:14 a.m. and 07:17 a.m. before resulting within acceptable range of 4.24 at 07:42 a.m.. E) Review of the Medonic all data summary report revealed that on 7/10/24 RBC high control lot# 2240303 with an acceptable range of 4.90 to 5.34 was resulted as 5.55, 5.55, 5.79, 5.51 between 07:18 a.m. and 07:20 a.m. before resulting within acceptable range of 5.09 at 07:43 a.m. F) Upon request, the laboratory was unable to provide documentation of corrective action taken when RBC quality control results failed to meet the defined acceptable ranges on 7/01/24 or 7/10/24. G) In an interview on 11/7/24 at 01:40 p.m., the laboratory staff member (number 4 on form CMS 209), when asked if the corrective action was documented for the instances identified above, stated "probably not". .