

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2226039	(X3) Date Survey Completed 03/20/2024
Name of Provider or Supplier Quest Diagnostics - Fort Smith Rrl	Street Address, City, State 6801 Rogers Ave, 1st Floor Lab, Fort Smith, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Review of laboratory policy and procedure "Beckman Coulter AU Operation for Automated Chemistry Tests" , quality control (QC) results for June 2023, notes for corrective action, instrument testing log for 6/20/24, patient result reports, and interview demonstrated that the laboratory failed to evaluate one of eleven patient result reports for sodium (NA) assays when QC results were outside of acceptable range and corrective action resulted in a change in the testing system. Findings follow: A) The laboratory policy and procedure "Beckman Coulter AU Operation for Automated Chemistry Tests" under "Addendum 4: Daily QC Information and Summary Log QC Summary Rules" states "(one control is greater than 3SD, QCM fails run. Repeat all patients)"and if "(two of three levels are greater than 2SD, both are H or both are L . Run fails.Repeat all patients)". B) Review of "instrument results inquiry" report for 6/20/23 reveals that at the end of "rack 4" run consisting of eleven patient reports Biorad QC lot # 77941, with an acceptable range for NA of (126.2 - 130.2), was reported as 123.1 with a flag indicating 3SD low at 1:27 p.m. with a corrective action note "recalibrate and rerun QC". At 2:10 p.m. three levels of QC were repeated and level 1 was reported as 125.7 with a flag indicating 2SD low while level 2 and level 3 were reported as within acceptable range and the corrective action note stated "recalibrate and rerun". All three levels of QC were repeated at 3:05 p.m.</p>

with level 1 reported as 124.7 with a flag of 3SD low, level 2 read 137.3 (acceptable range 137.4 - 141.4) with a flag indicating 2SD low, and level three read 157.2 (acceptable range 157.8 - 161.8) with a flag of 2SD low. Corrective action note stated "recalibrate and rerun QC, All three levels were repeated with acceptable results at 4:37 p.m. C) Review of patient results revealed that a NA assay was reported at 1:09 p.m. by "performing site: Mercy Fort Smith RRL, 6801 Rogers Avenue, Fort Smith, AR on patient KS191719A. D) Review of the "instrument results inquiry" revealed the last successful QC prior to the failures noted above was performed at 12:55 p.m. E) Upon request, the laboratory was unable to provide documentation that the NA result reported on patient KS191719A had been evaluated for accuracy. F) In an interview on 3/21/24 at 3:05 p.m., the laboratory staff member (#2 on the CMS 209 form) stated "it looks like we released that".