

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0712705	<b>(X3) Date Survey Completed</b>  03/13/2024
<b>Name of Provider or Supplier</b>  Nea Baptist Red Wolf Clinic	<b>Street Address, City, State</b>  3001 Apache Drive, Jonesboro, 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>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> 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: A review of the quality control (QC) results for February 2024, corrective action documentation, patient results, and interview revealed that patient results were not evaluated to the last successful QC performance when QC failed and corrective action made changes in the test system operation. Findings follow: A) Review of chemistry QC results for February 2024 revealed that on 2/21/24 Biorad Performance Verifier II lot# U1398 for sodium (NA) analysis (acceptable range 142.2 to 147.8). was resulted as 149.8 with flags "+ 3S" at 09:19 a.m , as 147.9 with flag of "+2s" at 09:50 a.m., as 139.5 with flag "-3s" at 11:23 a.m. . as 141.3 with flag "-2s" at 11:32 a.m.. with no acceptable result reported. B) Review of corrective action documentation for NA testing on that date revealed "changed ERF, reran, not in, new QC, reran X2 still out no patients ran" C) Review of NA QC results on 2/22/24 revealed performance verifier I lot # T1396 (acceptable range 115 to 120.6) was resulted 114.1 with a flag -2 S at 08:13 a.m.and repeated with a result of 114.2 with a flag of "-2S" at 09:25 a.m. before being acceptable with a result of 116.6 at 11:32 a.m. and performance verifier II lot # U1398 (acceptable range of 142.2 to 147.8) was resulted as 141.1 with flag of "-2S" at 08:15 a.m. and 141.3 with flag "-2S" at 09:25 a.m. before being acceptable with a result of 142.7 at 11:33 a.m. D) Review of corrective action documentation for NA testing on that date revealed "Fresh QC , New QC re-cal". The changing of ERF</p>

on 2/21/24 and recalibration on 2/22/24 represented a change in the testing system. E) Review of chemistry QC results for NA analysis revealed that the last successful QC for NA analysis was performed at 09:15 a.m. on 2/20/24. F) Review of patient results revealed that seven NA tests were performed and reported on 2/20/24 ( patient identified as numbers 1 through 7 on a separate patient identification list). G) In an interview on 3/23/24 at 03:45 p.m., the laboratory staff member (# 7 on the CMS 209 form) confirmed that the NA results reported on 2/20/24 had not been evaluated.