

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2300486	<b>(X3) Date Survey Completed</b>  01/22/2025
<b>Name of Provider or Supplier</b>  Siloam Springs Medical Center	<b>Street Address, City, State</b>  451 South Holly St, Siloam Springs, 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)(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: Based upon review of quality control (QC) reports for aspartate transaminase (AST) analysis for May 2024, the laboratory's "QC action Log", patient result reports for AST analysis, lack of documentation, and interview with laboratory staff, the laboratory failed to evaluate patient results back to the last QC performance on one of two months reviewed when QC results were unacceptable and corrective action taken represented a change in the testing system. Findings follow: A) Review of the QC results for AST analysis revealed that on 5/14/24, level 3 of Biorad Multiquel QC material, lot # 45930 with an acceptable range (210 - 238) was resulted as 209 at 09:19 a.m., 209 at 09:20 a.m., 206 at 10:12 a.m., 229 at 11:00 a.m. The last prior acceptable QC for AST analysis was performed on 5/13/24 09:15 a.m. B) review of the "QC Action Log" for AST on 5/14/24 revealed entries of "rerun didn't pass", calibration still didn't pass", opened new QC passed". The action of calibration represented a change in the testing system. C) Review of patient AST result reports revealed that AST analysis was performed and reported on 45 patients on 5/13/24 after successful QC performance. D) Upon request, the laboratory could not provide documentation that AST results performed on patients on 5/13/24 had been evaluated. E) In an interview on 1/22/25 at 09:15 a.m., laboratory staff members (numbers 2 and 3 on the form CMS 209) confirmed that the AST results reported on 5/13/24 had not been evaluated.</p>