

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468859	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Siloam Springs Medical Center	Street Address, City, State 451 South Holly Street, Siloam Springs, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Through a review of proficiency testing documentation, lack of documentation, and interviews with staff, it was determined the laboratory testing personnel and director failed to sign the attestation statements for one of eight proficiency testing events. Survey findings follow: A. A review of the proficiency testing documentation revealed the first chemistry testing event of 2021 had no signatures of testing personnel or director. B. In an interview on 7/20/2021 at 9:40am laboratory employee #2 (as listed on CMS form 209) confirmed that the forms lacked the required signatures.</p>
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:</p>

. Through review of quality control (QC) policy and procedure , QC results for June 2021, August 2021, May 2022, patient result listing reports, lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on five of five occasions in two of the three months reviewed when QC failed criteria for acceptability. Findings follow: A) Review of the laboratory policy and procedure revealed that action is to be taken when QC fails criteria for acceptability and "1 -3S a run is rejected when a single measurement exceeds the mean plus or minus 3SD and 2- 2S a run is rejected when 2 consecutive control measurements exceed the mean plus or minus 2SD control limit. B) Review of QC records for Alkaline Phosphatase (Alk PTase) test for June 2021 revealed that on 6/9/21 at 09:00 am Biorad Level 1 Control lot # 45861 with acceptable limits of 24 to 32 was resulted as 33 and on 6/10/21 at 09:00 the same control was resulted as 33 which was flagged as "2-2S". C) Review of documentation of corrective action for the event identified above revealed that the test system had been recalibrated which indicated a change in the test system operation. D) Review of QC results revealed the previous acceptable QC results for Alk PTase testing was performed on 6/8/21 at 09:35 am. E) Review of patient result listing reports revealed that a tests were performed and reported on 163 patients, identified as 1 through 163 on a separate patient identification list A, between 6/8/21 after 09:35 am and 6/9/21 before the system recalibration. F) Review of QC records for Triglyceride (Trig) test for June 2021 revealed that on 6/7/21 at 09:54 am Biorad Level 3 Control lot # 45861 with acceptable limits of 204 to 212 was resulted as 201 and 202 (flagged 2-2S) at 10:19 am. Acceptable QC result was logged at 10:40 am with corrective action documented as "recalibrated and passed"which indicated that the performance of the test system was changed. The previous acceptable QC results for Trig was on 6/4/21 at 09:33 am. G Review of patient result listing reports revealed that Trig tests were performed and reported on 50 patients, identified as numbers 1 through fifty on the separate patient identification list B, between 6/4/21 after 09:33 am and 6/7/21 before the system recalibration. H) Review of QC records for Sodium (Na) test for August 2021 revealed that on 8/4/21 at 10:17 am Biorad Level 3 Control lot # 45861 with acceptable limits of 156.9 to 160.9 was resulted as 162 (flagged 1-3S) at 10:13 am., resulted as 163 (flagged 1-3S) at 11:14 am Acceptable QC result was logged at 11:47 am with corrective action documented as "recalibrated and passed"which indicated that the performance of the test system was changed. The previous acceptable QC results for Na was on 8/3/21 at 10:00 am. I) Review of patient result listing reports revealed that Na tests were performed and reported on 77 patients, identified as numbers 1 through seventy-seven on the separate patient identification list C, between 8/3/21 after 10:00 am and 8/4/21 before the system recalibration. J) Review of QC records for Sodium (Na) test for August 2021 revealed that on 8/6/21 at 10:13 am Biorad Level 3 Control lot # 45861 with acceptable limits of 156.9 - 160.9 was resulted as 162 (flagged 1-3S) , resulted as 161 (flagged 2-2S) at 10:30 am Acceptable QC result was logged at 10:55 am with corrective action documented as "recalibrated and passed"which indicated that the performance of the test system was changed. The previous acceptable QC results for Na was on 8/5/21 at 10:31 am. K) Review of patient result listing reports revealed that Na tests were performed and reported on 58 patients, identified as numbers 1 through fifty-eight on the separate patient identification list D, between 8/5/21 after 10:31 am and 8/6/21 before the system recalibration. L) Review of QC records for Trig test for August 2021 revealed that on 8/9/21 at 10:27 am Biorad Level 1 Control lot # 45861 with acceptable limits of 91 to 99 was resulted as 88 (flagged 1-3S) , resulted as 88 (flagged 1-3S) at 11:02 am Acceptable QC result was logged at 11:26 am with corrective action documented as "took off old reagent recalibrated and passed"which indicated that the performance of the test system was changed. The previous

acceptable QC results for Trig was on 8/6/21 at 10:31 am. M) Review of patient result listing reports revealed that Trig tests were performed and reported on 37 patients, identified as numbers 1 through thirty-seven on the separate patient identification list E, between 8/6/21 after 10:31 am and 8/9/21 before the system recalibration. F) Upon request, the laboratory was unable to provide documentation that the patient testing identified in the citations above had been evaluated. G) In an interview on 6/20/22 at 11:10 am the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the tests identified in the citations above had not been evaluated and should have been.