Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468859	01/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Siloam Springs Medical Center	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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Through review of proficiency testing attestation forms and interview it was determined that the laboratory director did not attest that the proficiency testing was performed in the same manner as patient testing in two of eleven events reviewed. Survey findings follow: A) Review of API proficiency testing Chemistry Core second event 2018 and API proficiency testing Chemistry Miscellaneous second event 2018 revealed the laboratory director or designee did not sign the statement attesting that testing was performed in the same manner as patient testing . B) In an interview at approximately 10:35 AM on 1/17/20, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the laboratory director or designee signature was not present on the proficiency testing events attestation identified above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Through a review of the Architect c4000 and Architect i1000 Monthly Maintenance

	Logs for January 2019, March 2019, July 2019 and November 2019, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document maintenance with the frequency specified by the manufacturer in three of three months reviewed. Survey findings include: A) The Architect c4000 Montly Maintenance Log for March 2019, July 2019 and November 2019 has monthly maintenance requirements listed namely; "clean cuvette washer nozzles", "check syringes and valves", "clean ICT drain tip" and "check dispense components". The status record states "not performed" for all three months reviewed. . B) The Architect i1000 Monthly Maintenance Log for January March 2019, July 2019 and November 2019 has monthly maintenance requirements namely, "air filter cleaning" and the status record states "not performed" for all three months reviewed. C) Upon request the laboratory could not produce documentation that monthly maintenance had been performed on the Architect c4000 and Architect i1000 for the months identified above. D) In an interview at 4:15 p.m. on 1/16/20, the laboratorystaff member, identified as number 2 on the CMS 209 form, confirmed the lack of monthly maintenance documentation for the analyzers identified above..
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 "Laboratory Policy and Procedure: Abbott Architect Policy", "Quality Control Levy Jennings Reports", the laboratory's "QC Action Log" patient result list and interviewwith laboratory staff determined that the laboratory failed to document the evaluation of patient results back to the last successful quality control on two of ten analytes surveyed when quality control for Urea aand Alkaline Phosphatase (AlkP) assays failed to meet criteria for acceptability on 11/11/19. Findings follow: 1) The laboratory failed to document evaluation of 58 of 58 patient results back to the last successful quality control when quality control failed to meet criteria for acceptability for Urea assays. A) Review of "Laboratory Policy and Procedure: Abbott Architect Policy" stated "1-3S: A run is rejected when a single control measurement exceeds the mean plus or minus 3SD; 2-2S: A run is rejected when 2 consecutive control measurments exceed the same mean plus or minus 2SD". B) Review of the Urea "Levy-Jennings Report" November 2019 revealed the following results: Multiqual Level 3 Lot # 45800 expiration date 8/31/20 acceptable range (65 to 73) DATE TIME RESULT FLAG 11/08/19 0815 65 (acceptable) 11/11/19 0838 58 1 3S 11/11/19 0838 64 2 2S 11/11/19 0859 64 2 2S 11/11/19 0900 69 (acceptable) C) The "QC Action Log" dated 11/11 stated "Urea reran QC took old reagent off reran QC and passed" which indicated a change in the test system. D) Review of patient result listing revealed that 58 urea assays had been performed and reported since the last successful QC performance on 11/8/19 on patients identified as numbers 1 through 58 on a separate patient identification list. E) Upon request, the laboratory was unable to provide the documentation of the evaluation of Urea results performed and reported on 11/8/19 on the patients identified above.. F) In an interview on 1/16

	/20 at approximately 02:00 PM the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that quality control results for Urea identified above failed to meet criteria for acceptability and that evaluation of patient results back to the last successful QC event action was not documented. 2) The laboratory failed to evaluate 58 of patient AlkP results back to the last acceptable quality control on 11/8 /19 when quality control results failed to meet criteria for acceptability. A) Review of "Laboratory Policy and Procedure: Abbott Architect Policy" stated "1 3S: A run is rejected when a single control measurement exceeds the mean plus or minus 3SD; 2 2S: A run is rejected when 2 consecutive control measurments exceed the same mean plus or minus 2SD". B) Review of the AlkP "Levy-Jennings Report" November 2019 revealed the following results: Multiqual Level 3 1 Lot # 45800 expiration date 8/31 /20 acceptable range (285 to 325) DATE TIME RESULT FLAG 11/08/19 0814 305 (acceptable) 11/11/19 0836 269 1-3S 11/11/19 0928 273 1-3S 11/11/19 0948 267 1-3S 11/11/19 1014 287 (acceptable) C) The "QC Action Log" dated 11/11 stated "AlkP took old reagent off and reran " which indicated a change in the test system. D) Review of patient result listing revealed that 58 of 58 AlkP assays had been performed and reported since the last successful QC performance on 11/8/19 on patients identified as numbers 1 through 58 on a separate patient identification list. E) Upon request, the laboratory was unable to provide the documentation of the evaluation of AlkP results performed and reported on 11/8/19 on the patients identified above.. F) In an interview on 1/16/20 at approximately 02:00 PM the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that quality control results for AlkP identified above failed to meet criteria for acceptability and that evaluation of patient results back to the last successful QC event action was not documented.