Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468859	05/23/2018
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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Through a review of proficiency test scores for 2017 and 2018 and through interviews with laboratory staff, it was determined the laboratory quality assessment failed to prevent recurrence of proficiency test failures in two successive proficiency events. Survey findings include: A. Through a review of the proficiency test scores for API Hematology 3rd Event 2017, it was revealed the laboratory scored 50% on Sperm Presence / Absence. There was no corrective action documented for the failure. B. In and interview, at 10:22 on 5/23/2018, the technical consultant (as listed on the form CMS-209) confirmed the lack of corrective action for the 50% score. B. A review of the proficiency test scores for API Hematology 1st Event 2018 revealed the laboratory scored 50% on Sperm Presence / Absence. Failure to take corrective actions for the 3rd Event 2017 caused another failure on the 1st Event in 2018.
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 Diatron Abacus 3CP Monthly Maintenance Logs for January 2017 through May 2018, 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 two of seventeen months reviewed. Survey findings include: A. The Diatron Abacus 3CP Monthly Maintenance Log for January 2017 includes four weeks in which daily maintenance is documented (1/3/2017 through 1/7 /2017, 1/9/2017 through 1/13/2017, 1/16/2017 through 1/21/2017, and 1/23/2017 through 1/28/2017). B. The Diatron Abacus 3CP Monthly Maintenance Log for January 2017 has documentation of weekly maintenance in only two of four weeks in which the instrument was in use. Weekly maintenance was not documented in week 3 or week 4. C. The Diatron Abacus 3CP Monthly Maintenance Log for September 2017 includes four weeks in which daily maintenance is documented (9/5/2017 through 9/8/2017, 9/11/2017 through 9/16/2017, 9/18/2017 through 9/22/2017, and 9 /25/2017 through 9/30/2017). D. The Diatron Abacus 3CP Monthly Maintenance Log for September 2017 has documentation of weekly maintenance in only three of four weeks in which the instrument was used. Weekly maintenance was not documented in week 4. E. In an interview at 2:10 p.m. on 5/23/2018, the technical consultant (as listed on the form CMS-209) confirmed the lack of weekly maintenance documentation.
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: Through a review of laboratory policies and procedures, a review of November 2017, February 2018, and April 2018 monthly Levey - Jennings Reports and QC Results List Reports for the Architect chemistry analyzer, a review of the QC Action Log, a review of the Patient Result Listing report, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions taken when control materials failed to meet the laboratory's criteria for acceptability. Failure to take corrective actions for quality control failures has the potential to affect all testing performed. Survey findings follow: A. The policy titled "Abbott Architect C4000 and i1000" states, "The following Westguard multirules for acceptance of quality control results are used: 1 3S - A run is rejected when a single control measurement exceeds the mean plus or minus 3 SD [Standard Deviation]; 2 2S - A run is rejected when 2 consecutive control measurements exceed the same mean plus or minus 2SD control limit." B. The QC Results List Report for 11/3/2017 includes a result for Cholesterol Level 3 control of 290 which was reported at 8:19 a.m. and a result of 287 reported at 8:41 a.m. The result at 8:19 a.m. was flagged outside of 3 standard deviations and the result at 8:42 was flagged outside of 2 standard deviation. According to the laboratory 2 2S policy the run should be rejected. The only action documented on the QC Action Log on 11/10/2017 for Cholesterol Level 3 is, "will watch". C. The Cholesterol Patient Result Listing Report for 11/3/2017 includes 46

	patients reported. Patients reported include patients #149988, #283793, #172533, #154039, #282098, and #153891. D. The QC Results List Report for 11/10/2017 includes a result for Cholesterol Level 3 control of 287 which was reported at 8:26 a. m. and a result of 287 reported at 9:07 a.m. Both results were flagged outside of 2 standard deviation. According to the laboratory 2 2S policy the run should be rejected. The only action documented on the QC Action Log on 11/10/2017 for Cholesterol Level 3 is, "will watch level 3". E. The Cholesterol Patient Result Listing Report for 11/10/2017 includes 46 patients reported. Patients reported include patients #157782, #267049, #154790, #154277, #284941, and #144812 F. The February 2018, monthly Levey - Jennings Report includes a result on 2/5/2018 for Triglyceride Level 3 control of 188 which was flagged as 1-2s and a result on 2/6/2018 of 189 which was flagged with 1-2s. Both consecutive results were flagged outside of 2 standard deviation. According to the laboratory 2 2S policy the run should be rejected. The only action documented on the QC Action Log on 2/6/2018 for Triglyceride Level 3 is, "will watch". G. The Triglyceride Patient Result Listing Report for 2/6/2018 includes 50 patients reported. Patients reported include patients #143881, # 155072, #215349, #160024, #287032, and #148275. H. The February 2018, monthly Levey - Jennings Report includes a results on 2/16/2018 for Triglyceride Level 3 control of 188 (flagged with 1-2s), 187 (flagged with 1-3s), 187 (flagged with 1-3s), and 189 (flagged with 1-2s). Four consecutive results were flagged outside of 2 standard deviation. According to the laboratory 2 2S policy the run should be rejected. The QA Action Log for 2016 includes a note that level 3 was still flagged 1-2s after corrective actions were taken. I. The Triglyceride Patient Result Listing Report for 2/16/2018 includes 50 patients reported. Patients reported include patients #174299, # 151325, #149314, #203269, #163139, and #201839.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for four testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to give written authorization for four of four testing personnel to perform testing without direct supervision. Survey findings follow: A. Through a review of personnel records for the four laboratory testing personnel listed on the CMS-209, it was revealed that four of four personnel records failed to include an authorization signed by the director stating the procedures each testing personnel can perform and whether supervision is required. B. In an interview at 9:15 on 5/23/2018, the technical consultant (as listed on the form CMS-209) confirmed that four of four testing personnel authorizations were not signed by the laboratory director.