Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1036163	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health Medical Group	105 N Indian Meridian Rd, Pauls Valley, OK	

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
D0000	The findings were reviewed with the laboratory director and testing person #1 at the conclusion of the survey.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, observation, and interview with testing person #1, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed finger stick glucose testing using the Quintet AC glucometer and test strips; (2) Later in the survey, the surveyor observed the laboratory and identified the Quintet AC glucometer and one canister of Quintet AC test strips (Lot #211751625 with the manufacturer's expiration date of 06/09 /2018). There was no open date documented on the canister of test strips; (3) The surveyor reviewed the manufacturer's instructions as included on the canister of test strips, which stated "Discard when expired or 3 months after first opening;" (4) The surveyor removed the cap on the canister of test strips and identified 15 strips remained in the container (Unopened canisters contained 25 test strips). The surveyor asked testing #1 person if the glucometer and test strips had been used for patient testing. Testing person #1 explained the test strips and glucometer were very seldom used, but would be used for patient testing if needed. In addition, testing person #1 verified the open date of the test strips had not been documented; (5) The surveyor reviewed the manufacturer's instructions with testing person #1 who agreed the laboratory failed to follow the manufacturer's instructions to date new canisters of test strips with the open discard date.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed TSH (Thyroid Stimulating Hormone) testing using the NanoEnTek FREND test system; (2) The surveyor reviewed proficiency testing records from 2016 and 2017 and identified the following for TSH testing: (a) First 2017 event: (i) Although the laboratory obtained a score of 100%, the result of 1 of the laboratory's 5 specimens had not been evaluated by the proficiency testing program, due to "No Consensus" among the participants; (ii) In addition, the laboratory's result was "0.29." The proficiency testing program's acceptable response was "See Data Summary"; (iii) There was no documentation located in the records which proved the laboratory identified the non-graded response, obtained the data summary, and performed a self-evaluation to verify accuracy of the testing. (3) The surveyor then reviewed the proficiency testing program's "Performance Evaluation Sheet," which stated that, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded."; (4) The surveyor reviewed the findings with testing person #1, who agreed the laboratory had not identified the non-graded response, obtained the data summary, and performed a self-evaluation of the non-graded result.
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: Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: BECKMAN COULTER ACT 2 DIFF ANALYZER (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Beckman Coulter AcT 2 Diff analyzer; (2) The surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Daily: (i) Startup (ii) Shutdown (3) The surveyor reviewed records but could not locate maintenance records. The surveyor asked testing person #1 for the maintenance records. Testing person #1 explained any maintenance procedures performed were documented on the daily "Lab Testing Log"

	sheets; (4) The surveyor then reviewed the Lab Testing Logs from 4 months (January 2016; April and July 2017; and January 1 through January 24, 2018). There was no documentation the daily maintenance procedures had been performed during the 4 months reviewed; (5) The surveyor reviewed the records with testing person #1 who agreed there was no evidence the daily maintenance had been performed as required. NANOENTEK FREND ANALYZER (1) Testing person #1 stated to the surveyor TSH (Thyroid Stimulating Hormone) testing was performed using the NanoEnTek FREND test system; (2) The surveyor reviewed the manufacturer's daily maintenance instructions for the analyzer which were: (a) Power on the analyzer and view the main screen; (b) Perform and print the daily system check. Press "Item" to check System Check cartridge/code chip date; (c) Wipe analyzer using dry cloth. (3) The surveyor reviewed records but could not locate maintenance records. The surveyor asked testing person #1 for the maintenance records. Testing person #1 explained any maintenance procedures performed were documented on the daily "Lab Testing Log" sheets; (4) The surveyor then reviewed the Lab Testing Logs from 4 months (March and December 2016; and May and December 2017). There was no documentation the daily maintenance procedures had been performed during the 4 months reviewed. (5) The surveyor reviewed the records with testing person #1 who agreed there was no evidence the daily maintenance had been performed as required.