Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D1034952	01/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Medical Assoc-Siena Heights	2845 Siena Heights Dr, Henderson, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on January 14, 2019. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) proficiency testing reports for testing years 2017 and 2018 for Plasma Cardiac Markers and Hematology, a review of the laboratory responses to unacceptable proficiency testing results and an interview with the laboratory manager, the laboratory failed to review and evaluate the results of proficiency testing. Findings include: 1. The laboratory failed to develop a corrective action plan for the unacceptable response for PCAR-02 on the CAP PCARM-A 2018 proficiency test event. 2. The laboratory failed to develop a corrective action plan for the unacceptable response for PCAR-09 on the CAP PCARM-B 2018 proficiency test event. 3. The laboratory failed to evaluate and identify the unacceptable 20% CAP proficiency testing score for Hematocrit on the FH1-B 2017 proficiency testing event. The laboratory director's response was the out of range or unacceptable results for four of five proficiency test samples is less than 1.0 and therefore is not significant to alter the patient course of treatment. This was confirmed by the laboratory manager on January 14, 2019 at approximately 3:00 PM. The laboratory performs approximately 45,000 patient hematology tests annually.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual which addresses validation and verification of new tests and instrumentation, a review of the validation and verification for the new Medonic hematology analyzer and an interview with the laboratory manager, the laboratory failed to follow the director approved policy and procedure manual for the validation and verification of new laboratory instrumentation. Findings include: 1. The laboratory failed to follow the director approved policy and procedure for validation and verification of new laboratory instrumentation by testing level 1 and level 3 controls a minimum of 20 times each to show analytic precision. 2. The laboratory tested level 2 and level 4 twelve times each to show analytic precision. This was confirmed by the laboratory manager on January 14, 2019 at approximately 4:00 PM. The laboratory performs approximately 45,000 patient hematology tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random audit of eight patient laboratory testing from 4/03/17 through 11/20 /18, a review of quality control reports during the same time period and an interview with the laboratory manager, the laboratory failed to meet the laboratory's criteria for acceptability of quality control before reporting patient test results. Findings include: 1. A random audit of eight patients from 4/03/17 through 11/20/18 found that the quality control performed on the hematology analyzer on 3/16/18 did not meet the director approved policy of having at least two of three controls be within the acceptable range before reporting patient test results. 2. The autobackground check for the hematology analyzer was outside of the acceptable range. The result of the autobackground was 0.2 with a range of 0.0 to 0.1. There was no evidence of a repeat of the background check. 3. The level 1 quality control was outside of the acceptable range for WBC, RBC, Hemoglobin, MCV, Hematocrit and Platelet Count. There was no evidence of the level 1 quality control being repeated. 4. The level 2 quality control was outside of the acceptable range for Hematocrit. There was no evidence of the level 2 quality control being repeated. 5. The level 3 quality control was outside of the acceptable range for WBC, Lymph % and Lymph. There was no evidence of the level 3 quality control being repeated. 6. There were nine patient Complete Blood Count (CBC) results reported on 3/16/18. This was confirmed by the laboratory manager on January 14, 2019 at approximately 4:30 PM. The laboratory performs approximately 45,000 patient hematology tests annually.