Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0532041	07/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Marana Health Center	13395 N Marana Main St, Marana, AZ	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct inspection of Quality Control (QC) material for testing performed in the specialties of Chemistry and Hematology, review of laboratory test procedures and interview with the facility personnel, the laboratory failed to label QC reagents with the proper open expiration date. Findings include: 1. The laboratory performs testing on the Sysmex XS-1000i hematology analyzer with an approximate annual test volume of 42,036 and performs testing on the Cobas 311 and Cobas e411 Chemistry analyzers with an approximate annual test volume of 135,347. 2. Direct inspection of the QC reagents for the analyzers indicated above revealed the laboratory failed to indicate the proper open expiration date. 3. Review of the laboratory's Complete Blood Count (CBC) test procedures indicated the hematology QC (3 levels) has an open expiration date of 14 days. 4. Review of the laboratory's test procedures for Routine Chemistry and Endocrinology testing indicated the QC has an open expiration date ranging from 14 days to the printed expiration date, depending on the control material. The laboratory utilizes approximately 17 different controls for testing performed on the Cobas analyzers. 5. The facility personnel confirmed that the laboratory failed to label the control material indicated above with the proper open expiration dates. 4. The facility personnel confirmed that the laboratory failed to document the open expiration date on the Affirm reagents that were in use at the time of the survey.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the performance verification documentation for testing performed on the Cobas 311 and Cobas e411 analyzers and interview with the facility personnel, the laboratory failed to have the performance verification for each analyzer signed and approved prior to testing patient specimens. Findings include: 1. The laboratory began using two new analyzers, Cobas 311 and Cobas e411, in May 2018. The laboratory's approximate annual test volume for testing performed in the sub-specialties of Routine Chemistry and Endocrinology is 135,347. 2. No documentation was provided for review to indicate the laboratory director or technical consultant analyzed, approved and signed the performance verification data for each analyzer prior to patient testing. 3. The facility personnel confirmed that the laboratory did not have a signed, approved copy of the performance verification as indicated above.