Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0532041	03/24/2022
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
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: Based on review of proficiency testing (PT) records from 2021 for testing performed in the specialties of Chemistry and Hematology and interview with the facility personnel, the laboratory director failed to sign the PT attestation statements in a timely manner. Findings include: 1. The laboratory performs testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 275,226. 2. The PT attestation statements presented for review for the first event of 2021 for PT samples tested in the specialties of Chemistry and Hematology were signed and dated by the laboratory director on 3/23/2022. 3. The laboratory uses American Association of Bioanalysts (AAB) as their PT provider. The AAB PT schedule for the 1st event of 2021 for samples tested in Chemistry and Hematology indicated the result due date as 2/26/2021. 4. The facility personnel acknowledged that the laboratory director failed to sign the PT attestation statements indicated above at the time of the PT testing event which occurred in February 2021.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on lack of manufacturer's package inserts presented for review for testing performed on the Sysmex i-1000 Hematology analyzer, Roche C-311 Chemistry analyzer and Roche E-411 Endocrinology analyzer and interview with the facility personnel, the laboratory failed to retain the manufacturer's package insert for at least 2 years for each lot of Quality Control (QC) and Calibration material used on the analyzers by the laboratory. Findings include: 1. The laboratory performs patient testing using the Sysmex i-1000 Hematology analyzer, Roche C-311 Chemistry analyzer and Roche E-411 Endocrinology analyzer, with an approximate annual test volume of 275,226. 2. During the survey conducted on March 24, 2022, no evidence was presented for review to indicate the laboratory retained the manufacturers' assay information sheets for at least 2 years for each lot of QC and Calibration material that were used by the laboratory. 3. The facility personnel interviewed on March 24, 2022 at approximately 3:20pm confirmed that the laboratory failed to retain the manufacturers' assay information sheets for at least 2 years for each lot QC and Calibration material used on the analyzers indicated above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of employee competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess the competency of the Technical Consultant. Findings include: 1. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on March 24, 2022 listed one Technical Consultant who provides technical oversight for testing performed in the specialties of Chemistry and Hematology. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of the Technical Consultant. 3. The facility personnel confirmed that the laboratory did not have policies and procedures established to assess the competency of the laboratory personnel indicated above.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: (A) Based on review of Proficiency Testing (PT) records from 2020 and 2021, review of established Quality Assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow established QA policies to document corrective action for unsatisfactory PT scores for the regulated analytes, Cholesterol, HDL and Cell ID or WBC Diff; and (B) based on review of the laboratory's established QA policies and procedures, and interview with the facility

	personnel, the laboratory's QA procedures failed to identify and correct problems found with employee competency. Findings include: A1. The laboratory's established policy titled, "Proficiency Testing (LAB-30011)" states, "The laboratory is responsible for monitoring all PT discrepancies by the PT provider, therefore any unacceptable result must be investigated thoroughly to maximize the opportunity to correct a problem." The policy lists the following steps to take to conduct an investigation: Gathering and reviewing data, Evaluation of Patient results, Conclusions and Actions, and Documentation. A2. No documentation of corrective action was presented for review during the survey to indicate the laboratory followed their established policy referenced above to investigate and correct issues found with unacceptable PT scores received for Cell ID or WBC Diff from the 2nd event of 2021 and Cholesterol, HDL from the 1st event of 2021. See D5293 for specific findings. A3. The facility personnel confirmed that the laboratory failed to follow their established Proficiency Testing policy and procedure to document corrective action for the unsatisfactory PT scores referenced above. B1. The Technical Consultant performs and documents a monthly QA review to include the monitoring of employee competency. B2. The laboratory's QA processes failed to identify and correct issues found with missing competency evaluations for laboratory personnel. See D5209 and D6053 for specific findings. B3. The facility personnel confirmed that the monthly QA review performed by the Technical Consultant failed to identify and correct errors found with missing competency evaluations for laboratory personnel.
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: Based on review of the laboratory's Quality Assessment (QA) records and interview with the facility personnel, it was determined that the laboratory failed to document corrective actions taken to resolve problems associated with unsatisfactory Proficiency Testing (PT) scores. Findings include: 1. The laboratory performs patient testing in the specialties of Chemistry and Hematology, with an approximate annual test volume of 275,226. 2. The laboratory participates in PT under the specialty of Chemistry for the regulated analyte 'Cholesterol, HDL' and received an unsatisfactory score of 0% for the 1st testing event of 2021. 3. The laboratory participates in PT under the specialty of Hematology for the regulated analyte 'Cell ID or WBC Diff' and received an unsatisfactory score of 60% for the 2nd testing event of 2020. 4. No corrective action documentation was presented for review during the survey to indicate the laboratory resolved the problem of the unsatisfactory PT scores indicated above. 5. During the survey conducted on March 24, 2022 at approximately 1:48pm, the facility personnel confirmed the laboratory failed to document corrective action for the unsatisfactory PT scores indicated above.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity and number of deficiencies cited for quality practices identified during the survey conducted on March 24, 2022, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the specialties of Chemistry and Hematology. See D5437, D5469 and D5791 for findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration records for the Roche C-311 and Roche E-411 analyzers used for patient testing in the specialty of Chemistry and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory's calibration requirement for the Roche C-311 and Roche E-411 analyzers is to perform weekly calibrations on each analyzer. The testing personnel interviewed during the survey stated the Roche C-311 is calibrated each Tuesday and the Roche E-411 is calibrated each Wednesday. 2. No documentation was presented for review during the survey conducted on March 24, 2022 to indicate the laboratory performed and documented weekly calibration procedures as required for each analyzer indicated above prior to October 2020. 3. At approximately 3:35pm on 3/24/22, the facility personnel interviewed confirmed that the laboratory could not produce documentation of weekly calibration records prior to October 2020 for either analyzer indicated above. 4. The number of patients tested on the analyzers prior to October 2020 could not be determined at the time of the survey.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control

	materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, lack of QC lot correlation documentation and interview with the facility personnel, the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs patient testing using the Sysmex i-1000 Hematology analyzer, Roche C-311 Chemistry analyzer and Roche E-411 Endocrinology analyzer. 2. No documentation was presented for review during the survey conducted on March 24, 2022 to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzers indicated above from August 2019 through the date of the survey. 3. At approximately 3:25pm on March 24, 2022, the testing personnel interviewed confirmed that the laboratory failed to verify and document the criteria for acceptability of control lots used on the analyzers stated above. 4. The number of QC lots used on each analyzer from August 2019 through the date of the survey could not be determined 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: (A) Based on review of the laboratory's established Quality Assessment (QA) policies and procedures, review of Hematology and Chemistry Quality Control (QC) records and interview with the facility personnel, the laboratory failed to follow written policies and procedures in the analytic systems with regard to QC Lot Correlation activities; and (B) based on review of the laboratory's QA documentation, lack of calibration records for testing performed in the specialty of Chemistry and interview with the facility personnel, the laboratory's QA processes failed to identify and correct errors found with missing calibration records and other analytic test records. Findings include: A1. The laboratory performs patient testing using the Sysmex i-1000 Hematology analyzer, Roche C-311 Chemistry analyzer and Roche E-411 Endocrinology analyzer. It is the practice of the laboratory to perform 3 levels of QC material for Hematology testing and 2 levels of QC material for Chemistry testing, each day of patient testing. A2. The laboratory's established policy titled, "Lot-To-Lot QC Correlations (LAB-3-007)" states, "CLSI H26-H2 states new lots of control material be assayed in parallel with the current lot in use before the expiration of the current lot. Run each level of QC material as a patient sample would be performed twice a day for a total of five days. Calculated new mean values for each level. This new mean and SD can be used until a total of 30 samples has been collected for final lot ranges. Continue to perform QC on the new lot for 10 more days or for a total of

	30 values has been obtained. Compare the calculated mean values of each level to the values range specified on the manufacturer's insert. If the calculated mean is in range, they can be entered as the expected mean for the new lot of QC material. Close the old lot in the LIS. Enter the uploaded lot number, expiration date and assay ranges for the new lot of QC materials. Keep the correlation information for two years." A3. The laboratory failed to follow the established policy and procedure indicated above as evidenced by a lack of Lot-To-Lot QC Correlation data from 2019 through the date of the survey conducted on March 24, 2022. See D5469 for specific findings. A4. At approximately 3:35pm on March 24, 2022, the facility personnel confirmed that the laboratory failed to follow their established Lot-To-Lot QC Correlations policy referenced above for each lot of QC used by the laboratory for patient testing since 2019. B1. The Technical Consultant performs and documents a monthly QA review. The QA review monitors the following criteria: Lab Environment, Quality Assurance, Quality Control, Analyzer Maintenance, Semi-Annual QA, Annual QA, Periodic QA and Proficiency Testing. B2. The monthly QA review failed to monitor, identify and correct errors found with missing analytic records including calibration records prior to October 2020 from the Roche C-311 and Roche E-411 chemistry analyzers. See D5437 for specific findings. B3. The monthly QA review failed to monitor, identify and correct errors found with missing analytic records including package inserts from Quality Control and Calibration material used by the laboratory. See D3031 for specific findings. B4. The facility personnel confirmed that the laboratory's analytic QA processes were not effective at identifying and correcting the errors indicated above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Due to the number and severity of deficient practices identified during the survey conducted on March 24, 2022, the Condition of Laboratory Director was found to be not met as evidenced by: D6021 - failure to ensure the quality assessment program is maintained to assure the quality of laboratory services provided; D6023 - failure to ensure the maintenance of acceptable levels of analytical performance for each test system; and D6029 - failure to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of quality assessment policies and forms, the laboratory director failed to ensure that the quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5293, D5791 for findings.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on laboratory personnel interview and lack of calibration documentation for review, the laboratory director failed to ensure that acceptable levels of analytical performance for each test system were maintained. Findings include: 1. The laboratory failed to perform and document chemistry instrument calibration procedures as required. Refer to D5437.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for one testing personnel and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered. Findings include: 1. No initial training documentation was presented for review for one out of one testing personnel who began patient testing in February 2021. 2. During the survey conducted on March 24, 2022, at approximately 12:56pm, the facility personnel confirmed that the laboratory failed to provide documentation of initial training for the testing personnel indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on March 24, 2022, no 2020 annual competency evaluation documentation was presented for review for one out of one testing personnel. 2. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2020 for the testing personnel indicated above.