Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0882411	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cobre Valley Regional Medical Center	5880 South Hospital Drive, Globe, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records presented for review for 2019 and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for regulated analytes including pO2, pCO2 and pH for blood gas testing under the specialty of Chemistry and hemoglobin under the specialty of Hematology, which are included in subpart I. Findings include: 1. There was no documentation provided for review for the the first two PT events of 2019 for the analytes indicated above. 2. An invoice from the PT program dated September 16, 2019 was presented for review confirming enrollment for the third event of 2019. 3. Testing of patient specimens for the analytes noted above was not suspended during the first two PT events of 2019. 4. The laboratory tests approximately 3976 patients per year under the specialty of Chemistry and 1704 patients per year under the specialty of Hematology .
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons

	other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) scores received by the State, PT submission forms provided by the laboratory and interview with the laboratory personnel, the laboratory failed to submit PT results for blood gas testing within the timeframe indicated by the PT provider for the third event of 2018. Findings include: 1. The laboratory received unsatisfactory scores of zero for the regulated analytes pH, pCO2, and pO2 respectively for the third event of 2018. 2. The PT provider's results confirmation sheet indicated that the laboratory submitted the results on October 25, 2018, while the results submission deadline was October 24, 2018, attributing to the zeros received by the laboratory. 3. The laboratory provided no documentation of corrective actions or remedial actions conducted by the laboratory in regards to the late submission. 4. The laboratory personnel acknowledged that there was no documented corrective actions or remedial actions pertaining to the unsatisfactory scores received by the laboratory.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) scores received by the State, PT submission forms provided by the laboratory and interview with the laboratory personnel, the laboratory failed to submit PT results for hemoglobin testing within the timeframe indicated by the PT provider for the third event of 2018. Findings include: 1. The laboratory received an unsatisfactory score of zero for the regulated analyte hemoglobin under the specialty of Hematology for the third event of 2018. 2. The PT provider's results confirmation sheet indicated that the laboratory submitted the results on October 25, 2018, while the results submission deadline was October 24, 2018, attributing to the zeros received by the laboratory. 3. The laboratory provided no documentation of corrective actions or remedial actions conducted by the laboratory in regards to the late submission. 4. The laboratory personnel acknowledged that there was no documented corrective actions or remedial actions pertaining to the unsatisfactory scores received by the laboratory.
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 review of Proficiency Testing (PT) evaluations for 2018 and interview with the testing personnel, the laboratory failed to provide a documented review of the PT results for the first and second testing events in the the specialties of Chemistry and Hematology . Findings include: 1. No documentation of a review, including a written comment and signature, was presented during the survey to indicate the laboratory director or designee reviewed the PT results for two events in 2018. 2. There must be evidence of PT results reviewed even if the laboratory received a score of 100%. 3. The facility personnel confirmed that the PT results indicated above were not reviewed by laboratory director or designee.
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 lack of documentation provided by the laboratory from the proficiency testing (PT) organization and interview with the laboratory personnel, the laboratory failed to evaluate the results of the PT samples for the 3rd event of 2018 for blood gas testing compared to the results supplied by the PT organization. Findings include: 1. The laboratory received an unsatisfactory score of 0 for the third event of 2018 for blood gas testing since the PT results were not submitted to the PT organization by the deadline. 2. The laboratory provided no assessment of the PT results from the testing of the PT samples compared to the actual results supplied by the PT organization. 3. Prior to the survey conducted on 09/24/2019, the PT organization was not contacted by the laboratory regarding obtaining the actual results for comparative analysis.
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 a lack of a general quality assessment review and interview with the testing personnel, the laboratory failed to present a documented review of the quality assessment activities performed by the laboratory for 2018 and 2019.* Findings include: 1. No documented general quality assessment reviews were presented to the surveyor for 2018 and 2019. *2. This is a repeat deficiency cited from the survey

	conducted on 09/14/2017. The laboratory indicated that a policy was drafted stating that a general quality assessment review would be documented every quarter of each year. 3. The testing personnel acknowledged that there were no documented reviews for the timeframe stated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of an installation document provided to the laboratory by the manufacturer of the ABL80 blood gas instrument that was installed on 02/14/2019 and interview with the testing personnel, the laboratory failed to provide documentation indicating verification of performance characteristics for the instrument including accuracy, precision, reportable range and reference range. Findings include: 1. The document provided by the manufacturer indicated that calibrations and a verification kit that included quality control should be performed after the analyzer/monitor setup was completed. 2. There was no data presented that indicated calibrations were done or that the verification kit was utilized. 3. No documentation was presented for review of verification of performance characteristics including accuracy, precision, reportable range and reference range. 4. The testing personnel acknowledged that they did not know how to access the performance verification data.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent

	calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for blood gas testing and interview with the testing personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory currently performs blood gas testing on an ABL80 analyzer that was installed on 02/14 /2019. Prior to the installation of the ABL80 analyzer, the laboratory was performing blood gas testing using an i-Stat analyzer starting approximately on 11/02/2018. Before the i-Stat analyzer was used for patient testing, another ABL80 instrument was utilized until approximately 10/31/2018 when the machine broke down. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification for blood gas testing at least once every six months since 04/27 /2018 which the laboratory provided documentation, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. 3. The testing personnel acknowledged that they did not know if calibration verification was performed or not since 04/27/2018.
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: The Condition of Laboratory Director was found to be not met based on the failure to fulfill the director's responsibilities as evidenced by: D6013- Ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; D6015 -Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed; D6017 - Ensure that results are returned within the timeframes established by the proficiency testing program; D6018 - Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; D6021- Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on lack of performace documenation data presented for review, the director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. See D5421 for findings.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on lack of proficiency testing enrollment documentation presented for review, the laboratory director failed to ensure that the laboratory was enrolled in an HHS approved proficiency testing program for the first two events of 2019 for testing performed under the specialties of Chemistry and Hematology. See D2000 for findings.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of documentation provided to the laboratory by the proficiency testing (PT) program, the laboratory director failed to ensure that PT results were returned within the timeframes established by the proficiency testing program. See D2094 and D2128 for findings.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on lack of documentation presented for review, the laboratory director failed to ensure the review and evaluation of the laboratory's proficiency testing (PT) performance as reported by the PT program. See D5211 and D5215 for findings.
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 lack of quality assessment documentation for review, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D5293 for findings.