Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0882411	10/08/2024
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
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 Radiometer ABL80 and interview with the technical consultant (TC-2), the laboratory failed to retain the manufacturer's package inserts for at least 2 years for each lot of Quality Control (QC) used on the analyzer. Findings include: 1. The laboratory utilizes the Radiometer ABL80 to perform Blood Gas testing under the specialties of Chemistry and Hematology with an annual test volume of 13.340. 2. During the survey conducted on 10/8/24, no evidence was presented for review to indicate the laboratory retained the manufacturer's assay information sheets for at least 2 years for each lot of QC used on the Radiometer ABL80. 3. The TC-2 interviewed on 10/8/2024 at 11:45 AM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC used on the analyzer indicated above.
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 technical consultant (TC-2), the laboratory failed to verify the criteria for acceptability of quality control materials. Findings include: 1. The laboratory performs Blood Gas testing under the specialties of Chemistry and Hematology utilizing the Radiometer ABL80 analyzer with an annual test volume of 13,340. 2. No documentation was presented for review to indicate the laboratory verified the criteria for acceptability of each lot of control material used on the analyzer indicated above from 2022 through the date of the survey on 10/8/2024. 3. The TC-2 interviewed on 10/8/2024 at 11:45 AM confirmed the laboratory failed to document the criteria for acceptability of control lots used on the Radiometer ABL80. 4. The number of QC lots used on the analyzer from 2022 through the date of the survey could not be determined at the time of the survey.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a record review of competency assessments from 2023-2024, and interview with the technical consultant (TC-2), the technical consultant failed to evaluate the competency of testing personnel. Findings include: 1. The laboratory failed to provide evidence that indicated a qualified technical consultant performed and evaluated the semiannual competencies for one of one testing personnel. 2. The laboratory failed to provide evidence that indicated a qualified technical consultant performed and evaluated the 2023 annual competencies for two of eight testing personnel. 3. The laboratory failed to provide evidence that indicated a qualified technical consultant performed and evaluated the 2024 annual competencies for four of seven testing personnel. 4. The TC-2 interviewed on 10/8/24 at 09:30 AM confirmed the technical consultant failed to evaluate the competency of the above personnel.
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 technical consultant (TC-2), the technical consultant failed to evaluate and document the performance of one individual responsible for moderate complexity testing at least annually. Findings include: 1. No annual competency evaluation documentation from 2023 was presented for review for six of eight testing personnel who perform testing on the Radiometer ABL80. 2. No annual competency evaluation documentation from 2024 was presented for review for three of seven testing personnel who perform testing on the Radiometer ABL80. 2. The facility personnel interviewed on 10/8/24 at 9:30 AM confirmed the technical consultant failed to evaluate and document the performance of the testing personnel indicated above.