Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0531844	08/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Copper Queen Community Hospital	101 Cole Ave, Bisbee, 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
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: Based on review of Proficiency Testing (PT) records from 2020 and interview with the facility personnel, the laboratory failed to document corrective action for unsatisfactory PT scores for testing performed in the specialty of Chemistry. Findings include: 1. The laboratory received a score of 0% for the second PT event of 2020 for testing performed in the sub-specialties of Routine Chemistry (including Blood Gas testing), Endocrinology, and Toxicology. 2. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of unsatisfactory PT scores as indicated above. 3. The facility personnel confirmed that the laboratory failed to document corrective action for the unsatisfactory PT scores referenced 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 control practices identified during the survey conducted on August 4, 2021, 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 Microbiology, Chemistry and Hematology. See D5407, D5411, D5477 and D5791 for findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's test procedure and policy for the Gem 5000 blood gas analyzer and interview with the facility personnel, the laboratory failed to have the current laboratory director approve and sign the test procedure before use. Findings include: 1. The laboratory began testing on the Gem 500 blood gas analyzer in April 2020. 2. The "Blood Gas Policy and Procedure Manual" presented for review during the survey conducted on August 4, 2021 was not approved, signed and dated by the current laboratory director. 3. The facility personnel confirmed that the test procedure indicated above was not approved, signed and dated by the current laboratory director before use.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of coagulation test records, review of the manufacturer's package insert for coagulation reagents and interview with the facility personnel, the laboratory failed to use the correct International Sensitivity Index (ISI) value for each lot of Innovin reagent used on the coagulation analyzer. Findings include: 1. The laboratory performs patient testing on the Sysmex CA-660 coagulation analyzer. The laboratory performs approximately 150 'PT/INR' tests each month. 2. The analyzer uses a reagent called Innovin. The ISI value contained in the manufacturer's package insert from the Innovin reagent must be correctly programmed into the analyzer with each new lot of reagent used on the analyzer, to ensure the correct ISI value is used in the calculation of the International Normalized Ratio (INR). 3. During the survey conducted on August 4, 2021, at 4:00 pm, direct inspection of the Innovin reagent data entered into the analyzer revealed the following: Lot# 549735, ISI = 1.04. 4. During the survey conducted on August 4, 2021, at 4:01 pm, direct inspection of the manufacturer's package insert for the Innovin reagent used on the analyzer at the time of the survey revealed the following information: Lot# 549770, ISI = 1.01. 5. At approximately 4: 03 pm, on August 4, 2021, the testing personnel interviewed during the survey

	confirmed that the laboratory was currently utilizing Innovin lot# 549770, ISI = 1.01 on the Sysmex CA-660 analyzer used for patient testing, but the new lot information, including the ISI value, was not updated on the analyzer and the previous lot# and ISI value was still entered into the analyzer. 6. The laboratory failed to update the ISI value and new lot# for the current lot of Innovin reagent used on the analyzer at the time of the survey. 7. The laboratory failed to document the exact date in which the Innovin reagent (Lot# 549770, ISI = 1.01) was put into use for patient testing on the Sysmex CA-660 analyzer. 8. The number of patients tested using the incorrect ISI value could not be determined at the time of the survey. 9. The technical consultant for the specialty of Hematology interviewed during the survey confirmed that the laboratory failed to update the lot information and ISI value in the analyzer for the current lot of Innovin reagent used at the time of the survey, and failed to document the exact date in which the current lot of Innovin reagent was put into use for patient testing.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) documentation for Microbiology plated media and interview with the facility personnel, the laboratory failed to check each batch of media for sterility. Findings include: 1. The laboratory performs culture and sensitivity testing under the sub-specialty of bacteriology, with an approximate annual test volume of 8,192. 2. No documentation was presented for review during the survey conducted on August 4, 2021 to indicate the laboratory performed and documented sterility checks for the media used to perform culture testing on patient specimens. 3. The facility personnel confirmed that the laboratory failed to perform sterility checks on each batch of media used for culture testing.
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 Coagulation Quality Assessment (QA) records, coagulation test records and interview with the facility personnel, the laboratory's monthly QA process for Coagulation failed to identify and correct errors found with the ISI (International Sensitivity Index) value; (B) based on review of body fluid Quality Control (QC) documentation, review of the QC package insert and interview with the

facility personnel, the laboratory failed to document the acceptable ranges for body fluid control material tested with each patient test; and (C) based on review of patient blood gas test results, direct observation of the blood gas analyzer, review of Quality Assessment (QA) records and interview with the facility personnel, the laboratory's QA process failed to monitor, assess and correct problems identified with blood gas testing. Findings include: A1. The laboratory completes a monthly "Quality Assurance Monthly Summary Report" for Coagulation testing. The Monthly Summary Report contains a an area to mark 'yes' or 'no' to the following items related to Quality Control: Proper Controls utilized at required intervals prior to patient testing, Current QC range and lot in analyzer?, and Results graphed and reviewed for shifts/trends, and Corrective action taken and documented, when indicated. A2. During the survey conducted on August 4, 2021, at approximately 4:10 pm, the surveyor reviewed the monthly QA Summary Report for Coagulation, which was performed and documented by the General Supervisor on 8/02/2021 for the month of July 2021. The form had 'yes' marked to all the Quality Control monitors indicated above. A3. The completed monthly QA form for July 2021 referenced above failed to identify and correct the issue of the incorrect ISI value entered in the Sysmex CA-660 analyzer which is used for patient testing. See D5411 for findings. A3. The Technical Supervisor for Hematology interviewed during the survey confirmed that the laboratory's monthly QA process for Coagulation failed to identify and correct the error found with using the incorrect ISI value, which is used to calculate the patient's INR test result. B1. The laboratory performs manual body fluid counts on patient specimens in the specialty of Hematology. B2. It is the practice of the laboratory to test two levels of body fluid QC in duplicate with each patient test performed. The laboratory uses a worksheet to document the results of both levels of QC, including both counts. The worksheet contains an area listed as "QC Level 1 Lot#" and "QC Level 2 Lot #" in which the testing personnel performing the test documents the QC lot # and expiration date for each level of control material tested. B3. The laboratory failed to document the acceptable range for each level of control material as evidenced by review of the worksheet for patient# 1208052 tested on July 21, 2021. The worksheet listed QC Level 1 Lot #136122, expiration date 2-28-23 and QC Level 2 Lot #136121, expiration date 2-28-23. The QC results listed for Level 1, included RBC's (A) 2 and (B) 4 and WBC's (A) 3 and (B) 1. The QC results listed for Level 2, included RBC's (A) 10 and (B) 15 and WBC's (A) 17 and (B) 11. B4. No evidence was presented for review to determine if the QC results listed above were within the manufacturer's stated range. B5. During the survey conducted on August 4, 2021, laboratory personnel stated that the QC ranges for each level of QC material indicated above were listed in manufacturer's package insert, however the manufacturer's package insert containing the acceptable ranges for each level of QC indicated above was not readily accessible when requested by the surveyor. B6. The facility personnel acknowledged that the laboratory failed to document the acceptable ranges of body fluid QC for each level of QC material tested by the laboratory, in order to determine if the QC performed was acceptable or not. C1. The laboratory began patient testing on the Gem 5000 blood gas analyzer in April 2020. C2. The laboratory's established policy titled, "Arterial Blood Gas Process" states that the sample is invalid if "Analysis is delayed (greater than 15 minutes for samples held at room temperature or greater than 60 minutes for samples held at 4 degrees Celsius)." C3. Review of patient test report (MR# 1210165) for Arterial Blood Gas testing performed on 6/25/2021 indicated the time drawn as 3:00pm and instrument printout listed the time the sample was analyzed as 14:48:45 on 6/25/21. C4. During the survey conducted on August 4, 2021, at 3:06 pm (verified by both the surveyor and Technical Consultant), direct observation of the Gem 5000 analyzer by the surveyor and the Technical Consultant revealed that the time indicated on the analyzer was showing as 14:42. C5. The

	laboratory performs and documents a monthly QA review specific to testing performed on the Gem 5000 to include: Quality Control (including problems with patient testing), Proficiency Testing Surveys, Supply Issues and Customer Service Complaints. C6. No evidence was presented for review during the survey to indicate the laboratory's monthly QA process identified and corrected the issue found with the incorrect time entered into the Gem 5000 analyzer. C7. The facility personnel acknowledged that the laboratory's QA process failed to identify and correct the issue found during the survey, revealing that the time was showing incorrectly on the Gem 5000 analyzer.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6042 - failure to ensure that a Quality Control program is maintained and failure to ensure that acceptable levels of analytic performance were maintained throughout the entire testing process.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on errors identified during the survey for the Coagulation test system, the technical consultant failed to ensure that the parameters for acceptable levels of analytic performance are maintained throughout the entire testing process. See D5411 for findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) documentation, the laboratory director

	failed to ensure that a QA program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291 and D5791 for findings.