

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0531844	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Copper Queen Community Hospital	Street Address, City, State 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct inspection of the current in use quality control (QC) material for CBC's, and interview with the laboratory personnel, the laboratory failed to include the new expiration date of the QC material based on the opened date that the laboratory personnel indicated on each QC tube. Findings include: 1. Each CBC QC tube indicated the open date with no new expiration date which according to the manufacturer's package insert is 7 days from the open date. 2. The laboratory personnel stated that the QC material was always used up prior to the new expiration date.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
 Based on lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed on the Medtox analyzer. Findings include: 1. The laboratory began testing under the sub-specialty of Toxicology using the Medtox analyzer in March 2017. On the date of the survey, November 6, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, once each week and/or each new shipment or lot of test reagents. 2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of external quality control material of different concentrations each day of patient testing as required since January 1, 2016. The laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test system. 3. The facility personnel confirmed that the laboratory did not perform and document controls as required and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the Medtox analyzer. 4. The laboratory tests approximately 140 patients annually using the Medtox test system.

D5449

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on review of one patient report (MRN #356458) from 07/28/2017, the laboratory's Alere Clostridium Difficile (C. Diff) quality control log and interview with laboratory personnel, the laboratory failed to perform a positive and negative control on 07/28/2017, the day that the patient was tested. Findings include: 1. The Alere C. Diff quality control log for the month of July 2017 did not have an entry for both the positive control and negative control for 07/28/2017, the day that the patient specimen was collected, tested and reported out. 2. The laboratory personnel could not explain why there was no QC entry for 07/28/2017. 3. It was not determined at the time of the survey if any other patients were tested for C. Diff on 07/28/2017.

D5775

COMPARISON OF TEST RESULTS
 CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
 Based on review of test comparison results from 2017 and 2018 and interview with

the facility personnel, the laboratory failed to perform an instrument to instrument comparison at least twice a year for testing performed on two of the same instruments. Findings include: 1. The laboratory utilizes two separate Beckman Coulter AU480 chemistry analyzers to perform testing. The laboratory's approximate annual test volume in the sub-specialty of Routine Chemistry is 263,936. 2. During the survey conducted on November 6, 2018, no documentation was presented for review to indicate the laboratory performed a comparison of the test results from the two instruments at least twice a year. The laboratory performed a test result comparison on March 3, 2017 and October 17, 2018. 3. The facility personnel confirmed that the laboratory failed to perform a test result comparison at least twice annually for testing that is performed on the AU480 analyzers.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the laboratory's information system (LIS). Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology and Immnuohematology, with an approximate annual test volume of 376,628. It is the practice of the laboratory to manually enter test results into the LIS for the following tests: KOH, Wet Mount, Gram Stain, C. Difficile, Shiga A/B stool, Manual Differentials, Urine Microscopic, RF (Rheumatoid Factor), Serum hCG and Blood Gas testing performed on the I-stat analyzer. 2. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered into the LIS. 3. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are manually entered by the testing personnel into the LIS.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 control records and control procedures, the laboratory

director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 for findings.