

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2124326	(X3) Date Survey Completed 04/25/2018
Name of Provider or Supplier Copper Queen Community Hospital	Street Address, City, State 100 E 5th St, Douglas, 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
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> <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 Alere analyzer. Findings include: 1. The laboratory began D-dimer, CK-MB and Troponin testing under the specialty of Hematology and Chemistry using the Alere analyzer on April 4, 2017. On the date of the survey, April 25, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, once each month 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. 4. 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 Alere analyzer. 5. The number of patients tested on the Alere analyzer could not be determined at the time of the survey.</p>

D5543

HEMATOLOGY

CFR(s): 493.1269(a)(d)

(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of patient test records and interview with the testing personnel it was determined that the laboratory failed to document duplicate cell counts using a hemocytometer. Findings include: 1. The laboratory performs a manual cell count on Cerebrospinal Fluid (CSF) using a hemocytometer and uses a worksheet to record the count. 2. Review of the laboratory's worksheet for patient# 1203212 on 10/27/17 indicated the laboratory performed a CSF count but did not document the count in duplicate. 3. The testing personnel confirmed that the counts are performed in duplicate but the laboratory failed to document both counts.

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:

Based on review of Quality Assessment (QA) documentation and policies and interview with the facility personnel, the laboratory failed to have written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory monitored or identified problems with analytic activities, including but not limited to, quality control procedures for the Alere analyzer. See D5445 for findings. 2. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to monitor specific areas of the analytic systems as indicated above.

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 specialty of Microbiology, Chemistry, Hematology and Immnuohematology, with an approximate annual test volume of 29,740. It is the practice of the laboratory to manually enter test results into the LIS for the following tests: KOH, Wet Mount, Gram Stain, ABO/Rh, and testing performed on the I-stat analyzer (Arterial Blood Gas and PT/INR). 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.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

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 include on the test report the laboratory address where the testing was performed. Findings include: 1. The laboratory performs patient testing in the specialty of Microbiology, Chemistry, Hematology and Immnuohematology, with an approximate annual test volume of 29,740. 2. Six out of six test reports reviewed during the survey were missing the laboratory address where the testing was performed. 3. The facility personnel confirmed that the laboratory address where the testing was performed was not indicated on the test reports referenced above.