

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2124326	<b>(X3) Date Survey Completed</b>  02/20/2020
<b>Name of Provider or Supplier</b>  Copper Queen Community Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the facility personnel, the laboratory failed to document corrective action for unsatisfactory PT scores. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing, including a manual differential if warranted. The laboratory's approximate annual test volume for the specialty of Hematology is 54,000. 2. The laboratory is enrolled in PT for Blood Cell Identification, to include "Blood Cell ID (Educational)" which includes five samples each PT event. The results of this particular test are not evaluated by the PT organization and given a performance result of "Not Graded". It is the laboratory's responsibility to self-grade the results by comparing the reported results against the expected results provided by the PT organization once the PT results are returned to the laboratory. 3. During the survey conducted on February 20, 2020, review of the PT records from 2018 and 2019 indicated the laboratory failed to document a self-evaluation for the Blood Cell ID (Educational) results. 4. The facility personnel confirmed that the laboratory failed to document a self-evaluation for Blood Cell ID (Educational) PT results during 2018 and 2019.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and</p>

test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's criteria for relative humidity requirements for the environment where the Sysmex hematology analyzer is operated, the humidity range indicated on the laboratory's log sheets and interview with the facility personnel, the laboratory failed to follow manufacturer's instructions for the humidity levels where the Sysmex hematology analyzer is operated. Findings include: 1. The laboratory performs patient testing on the Sysmex XN 550 hematology analyzer, with an approximate annual test volume of 54,000. 2. The manufacturer's specifications for the relative humidity (RH) are between 30% and 95% with no condensation. 3. The laboratory's logs indicated an acceptable humidity range of between 8% and 80%. 4. The facility personnel acknowledged that the laboratory's established humidity range was not consistent with the manufacturer's requirements.