

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0531844	(X3) Date Survey Completed 07/31/2024
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of manufacturer's package inserts presented for review for the manual Cerebrospinal fluid (CSF) cell counts performed by the laboratory and interview with the Technical Supervisor (TS-2), the laboratory failed to retain the manufacturer's package insert for at least 2 years for each lot of Quality Control (QC) used. Findings include: 1. During the survey conducted on 7/31/2024, 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 for the manual CSF cell counts performed by the laboratory. 2. The TS-2 interviewed on 7/31/2024 at 10:40 AM confirmed the laboratory failed to retain the manufacturer's assay information sheets for at least 2 years for each lot of QC for the testing indicated above. 3. The laboratory performs approximately five CSF counts on patients per year under the specialty of Hematology.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for</p>

the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on lack of performance specification documentation for the Minicube analyzer and interview with the technical supervisor I (TS-2), the laboratory failed to verify the manufacturer range and reportable range for the Minicube analyzer prior to reporting patient test results. Findings include: 1. The laboratory began using the Minicube analyzer to perform Erythrocyte Sedimentation Rate (ESR) testing on patients in May 2022. 2. The laboratory failed to demonstrate that it can obtain the manufacturer range and reportable range comparable to that established by the manufacturer for the Minicube analyzer prior to reporting patient test results. 3. The TS-2 interviewed on 7/31/24 at 8:50 AM confirmed the laboratory failed to verify the manufacturer range and reportable range for the Minicube analyzer prior to reporting patient test results. 4. The laboratory performs approximately 35 ESR tests on patients per month.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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-- (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.

This STANDARD is not met as evidenced by:

Based on lack of Quality Control (QC) documentation and interview with the Technical Supervisor (TS-2), the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Hematology. Findings include: 1. The laboratory began using the Minicube analyzer to perform Erythrocyte Sedimentation Rate (ESR) on patients under the specialty of Hematology in May 2022. 2. The laboratory failed to perform two levels of external quality control on the Minicube analyzer on 5/6/2022. 3. On 5/6/2022, ESR testing was performed on five patients. 4. The TS-2 interviewed on 07/31/2024 at 1:15 PM confirmed the laboratory failed to perform and document two levels of external control material on the Minicube analyzer on 5/6/2022.