

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0531844	(X3) Date Survey Completed 09/30/2024
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
D0000	Based on a proficiency testing desk review survey performed on September 30, 2024, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director, high complexity
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Enhanced Reporting (CASPER) 155 report and American Proficiency Institute's (API) proficiency testing records, the laboratory failed to successfully participate in two of three consecutive testing events</p>

	<p>in the subspecialty of Immunohematology for the regulated test, Compatibility Testing in 2024 resulting in an initial unsuccessful performance. Refer to D2181. 1. The laboratory's PT performance was unsatisfactory for the first event of 2024 as indicated below: - Compatibility Testing - 80% 2. The laboratory's PT performance was unsatisfactory for the second event of 2024 as indicated below: - Compatibility Testing - 80%</p>
<p>D2181</p>	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CASPER 155 report and American Proficiency Institute (API), PT records from 2024, the laboratory failed to achieve satisfactory performance (100%) for two of three testing events in the subspecialty of Immunohematology for the test, Compatibility Testing. Findings include: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: 2024 event 1, Compatibility Testing 80% 2024 event 2, Compatibility Testing 80% 2. A review of the proficient testing scores from API (2024) confirmed the above findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 Individual Laboratory Report and American Proficiency Institute (API), and 2024 records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER-0155 and American Proficiency Testing (API) 2024-1 and 2024-2, evaluation reports, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2181.</p>