

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2124326	(X3) Date Survey Completed 05/16/2023
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
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 Proficiency Testing (PT) reports for 2022 and 2023 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analyte, AST(SGOT), under the subspecialty of Routine Chemistry, and the regulated analyte, Phenytoin, under the subspecialty of Toxicology, resulting in unsuccessful PT performance. Findings include: 1. The laboratory's PT performance was unsatisfactory for the first event of 2023 for the regulated analyte, AST(SGOT), with a score of 60%. 2. The laboratory's PT performance was unsatisfactory for the second event of 2023 for the regulated analyte, AST(SGOT), with a score of 60%. 3. Unsatisfactory participation in the first and</p>

	<p>second events of 2023 (two consecutive testing events) for the regulated analyte, AST (SGOT), constitutes unsuccessful PT performance. 4. The laboratory's PT performance was unsatisfactory for the second event of 2022 for the regulated analyte, Phenytoin, with a score of 20%. 5. The laboratory's PT performance was unsatisfactory for the first event of 2023 for the regulated analyte, Phenytoin, with a score of 60%. 6. Unsatisfactory participation in the second event of 2022 and first event of 2023 (two out of three consecutive testing events) for the regulated analyte, Phenytoin, constitutes unsuccessful PT performance.</p>
<p>D2094</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnished to the State Agency for 2023, the laboratory failed to undertake appropriate training, technical assistance and remedial action necessary to correct problems associated with proficiency test failures for the regulated analyte, AST(SGOT). See D2016 for findings.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, AST(SGOT), for the first and second testing events of 2023 resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D2116</p>	<p>TOXICOLOGY CFR(s): 493.845(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

	<p>This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnished to the State Agency for 2023, the laboratory failed to undertake appropriate training, technical assistance and remedial action necessary to correct problems associated with proficiency test failures for the regulated analyte, Phenytoin. See D2016 for findings.</p>
<p>D2118</p>	<p>TOXICOLOGY CFR(s): 493.845(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, Phenytoin, for the 2nd event of 2022 and 1st event of 2023 resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D3031</p>	<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 instrument printouts generated from the Triage Meter analyzer and interview with the technical consultant (TC-1), the laboratory failed to retain patient test records, including instrument printouts, for at least 2 years. Findings include: 1. The laboratory performs Brain Naturemic Peptide (BNP) testing on the Triage Meter analyzer under the specialty of Chemistry. 2. No documentation was presented for review during the survey conducted on May 16, 2023 to indicate the laboratory retained instrument printouts from the Triage Meter analyzer for at least 2 years. 3. The TC-1 interviewed on May 16, 2023 at 2:15 PM confirmed the laboratory failed to retain instrument printouts from the Triage Meter for at least 2 years.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of employee competency policies and procedures for review and interview with the technical supervisor (TS-1), the laboratory failed to establish policies and procedures to assess the competency of the Technical Consultant (TC), Technical Supervisor (TS) and General Supervisor (GS). Findings include: 1. The</p>

CMS-209, Laboratory Personnel form submitted for review during the survey conducted on May 16, 2023 listed two TC's, three TS's and one GS who provide technical oversight for testing performed in the specialties of Microbiology, Chemistry, Hematology and Immunohematology. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of the TC's, TS's and GS. 3. The TS-1 interviewed on May 16, 2023 at 12:05 PM confirmed the laboratory failed to have policies and procedures established to assess the competency of the laboratory personnel indicated above.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on lack of calibration verification documentation for the Sysmex XN550 hematology analyzer and interview with the technical supervisor (TS-1), the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory uses a Sysmex XN550 analyzer to perform Complete Blood Count (CBC) testing in the specialty of Hematology. The laboratory's reported annual test volume for the specialty of Hematology is 23,960. 2. No documentation was presented for review from 2022 through May 16, 2023 to indicate the laboratory performed a calibration verification at least once every six months, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. Records reviewed for the Sysmex XN500 indicated a calibration verification was last performed on 11/05/2021. 3. The TS-1 interviewed on May 16, 2023 at 1:45 PM confirmed the laboratory failed to perform calibration verification activities on the Sysmex XN500 analyzer during 2022 through the date of the survey.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) records, lack of QC documentation and interview with the technical consultant (TC-1), the laboratory failed to establish the statistical parameters for unassayed control materials used by the laboratory for Coagulation testing. Findings include: 1. The laboratory performs Coagulation testing on the Hemochron analyzer. It is the practice of the laboratory to utilize commercially available control material. The laboratory performs the following tests: Protime (PT/INR). 2. Review of QC logs for PT/INR records indicated that the laboratory utilized a previously tested patient specimen instead of the commercially available Control Level 1 on April 29, 2022. 3. No documentation was presented for review to indicate the laboratory established the criteria for acceptability of the patient specimen used by the laboratory as a substitute for control level 1 on April 29, 2022. 4. At 3:20 PM on May 16, 2023, the TC-1 interviewed confirmed that the laboratory failed to establish the criteria for acceptability of control materials used on the Hemochron analyzer on April 29, 2022. 5. Approximately 1 patient test for PT/INR was performed on April 29, 2022.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of Quality Control (QC) documentation and interview with the technical supervisor (TS-1), the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics for testing performed in the specialty of Hematology. Findings include: 1. The laboratory performs testing in the specialty of Hematology, with an approximate annual test volume of 23,960. 2. It is the practice of the laboratory to perform a manual differential on blood smears using a differential stain (Wright Stain), if the specimen meets certain criteria established in the laboratory's procedure manual. 3. Review of the Daily Wright Stain Check log from April 2022 used by the laboratory to record the Wright Stain acceptability failed to indicate the acceptability of the Wright Stain material on April 2, April 16, April 23 and April 30, 2022. 4. The TS-1 interviewed on May 16, 2023 at 1:30 PM confirmed the laboratory failed to test staining materials for intended reactivity to ensure

predictable staining characteristics in April 2022 as indicate above. 5. The number of patients tested with this stain could not be determined at the time of the survey.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (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 Quality Control (QC) records and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document two levels of control material each 8 hours of operation for Coagulation testing performed in the specialty of Hematology. Findings include: 1. The laboratory performs Coagulation testing on the Hemochron analyzer in the specialty of Hematology. The laboratory's hours of operation are reported as 24 hours a day, 7 days a week. 2. Review of the laboratory's QC logs indicated the laboratory failed to perform two levels of control material each 8 hours of operation for Protime/INR (PT/INR) testing for the following dates in April 2022: April 1st - 9th, April 12th, April 13th, April 15 - 21, and April 29th. 3. Review of the laboratory's QC logs indicated the laboratory failed to perform two levels of control material each 8 hours of operation for Activated Partial Thromboplastin Clotting Time (APTT) testing for the following dates in April 2022: April 4th - 9th, April 12th, April 13th, April 16, April 18 - 19th. 4. The TC-1 interviewed on May 16, 2023 at 3:18 PM confirmed the laboratory failed to perform two levels of control material each 8 hours of operation for PT/INR and APTT during April 2022. 5. The laboratory performed 58 PT/INR tests on the dates indicated above (see #2). 6. The laboratory performed 22 APTT tests on the dates indicated above (see #3).

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) policies and procedures, analytic test records, and interview with the technical supervisor (TS-1), the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory performs a monthly QA summary report for each department (instrument/test system) performed by the laboratory. 2. The QA summary report reviewed during the survey for April 2022 for "Hemochron Coagulation" failed to identify problems found with the frequency of Coagulation Control material performed by the laboratory, see D5445 for findings. 3. The QA summary report reviewed during the survey for April 2022 for "Hemochron Coagulation" failed to identify problems found with using previously tested patient

	<p>specimens as control materials, in which the laboratory failed to establish the the criteria for acceptability of these control materials, see D5469 for findings. 4. The TS-1 interviewed on May 16, 2023 at 3:50 PM confirmed the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the analytic systems.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation and interview with the technical consultant (TC-1), the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No evidence of a semiannual competency evaluation was presented for review for one out of one testing personnel who began testing in the specialties of Microbiology, Hematology and Chemistry in January 2022 2. The TC-1 interviewed on May 16, 2023 at 11:55 AM confirmed the laboratory failed to document a semiannual competency evaluation for one testing personnel as indicated above.</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: The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6089 - ensuring that proficiency testing samples are tested as required under Subpart H and D6093 - failure to ensure quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</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 information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analytes, AST(SGOT) and Phenytoin. See D2016 and D6076 for findings.</p>

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 D5469 and D5545 for findings.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of documentation of a semi-annual competency evaluation for one testing personnel and interview with the technical supervisor (TS-1), the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. No evidence of a semi-annual competency evaluation was presented for review for one out of one testing personnel who began testing in the specialties of Microbiology, Hematology and Immunochemistry in January 2022. 2. The TS-1 interviewed on May 16, 2023 at 11:55 AM confirmed that the technical supervisor failed to document a semi-annual competency evaluation for the testing personnel indicated above.