

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0706385	(X3) Date Survey Completed 08/29/2023
Name of Provider or Supplier Northern Cochise Community Hospital	Street Address, City, State 901 W Rex Allen Dr, Willcox, 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, Digoxin, under the specialty of Chemistry. Findings include: 1. The laboratory's PT performance was unsatisfactory for the 3rd event of 2022 for the regulated analyte, Digoxin, with a score of 60%. 2. The laboratory's PT performance was unsatisfactory for the 1st event of 2023 for the regulated analyte, Digoxin, with a score of 60%. 3. Unsatisfactory participation in the 3rd event of 2022 and 1st event of 2023 (two consecutive testing events) for the regulated analyte, Digoxin, constitutes an initial unsuccessful PT performance.</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, Digoxin for the 3rd event of 2022 and 1st event of 2023 resulting in unsuccessful PT performance. See D2016 for findings.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the Technical Supervisor (TS-2), the laboratory failed to verify the accuracy of Body Fluid analysis testing at least twice annually during 2022. Findings include: 1. No documentation was presented for review during the survey conducted on August 29, 2023 to indicate the laboratory verified the accuracy of Body Fluid examinations at least twice annually during 2022. 2. The TS-2 interviewed at 11:40 AM confirmed the laboratory failed to verify the accuracy of the testing indicated above at least twice annually during 2022.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of maintenance logs for the AU480 Chemistry Analyzers and interview with the Technical Consultant (TC-2), the laboratory failed to perform and document the weekly maintenance as required by the manufacturer. Findings include: 1. The laboratory performs testing on two separate AU480 Chemistry analyzers, referred to by the laboratory as AU480 #1 and AU480 #2. 2. Review of the AU480 Maintenance logs for AU480 #1 and AU480 #2 indicated the laboratory failed to document the weekly maintenance for one out of four weeks in August 2023, for each analyzer. 3. The AU480 weekly maintenance includes: Clean Sample Pre-Dilution Bottle, Perform a W2 and Perform a Photocal. 4. On August 29, 2023 at 1:37 PM, the TC-2 interviewed acknowledged the maintenance activities listed above were not performed and documented for the week listed above. 5. The laboratory's reported annual test volume for the specialty of Chemistry is 122,109.</p>

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 one of two AU480 chemistry analyzers and interview with the Technical Consultant (TC-2), the laboratory failed to perform and document calibration verification procedures at least once every 6 months during 2022 and 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory performed a calibration verification on the AU480 chemistry analyzer (system ID# 65355400) at least once every six months during 2022 and 2023, 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. 2. The TC-2 interviewed on August 29, 2023 at 1:33 PM confirmed the laboratory failed to perform calibration verification procedures on the chemistry analyzer indicated above during 2022 and 2023 (as of the survey date). 3. The laboratory's reported annual test volume in the specialty of Chemistry is 122,109.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (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, lack of sterility documentation

and interview with the Technical Supervisor (TS-2), the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and failed to check each batch of media for sterility. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Bacteriology, with an annual approximate test volume of 3,193. 2. Review of plating media in use on the day of the survey, August 29, 2023, revealed the laboratory failed to check each batch of media for sterility and failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms prior to using the media for patient testing. QC and sterility documentation were missing for the following media: - Macconkey (MAC) media, lot# 703540, expiration date 9/26/23, received by the lab on 7/26/23 - Blood Agar (TSA w/ Sheep Blood), lot# 720640, expiration date 10/23/23, received by the lab on 8/25/23 - Columbia CNA agar w/ 5% Sheep Blood, lot# 703810, expiration date 9/20/23, received by the lab on 7/28/23 - Chocolate Agar, lot# 703605, expiration date 9/27/23, received by the lab on 7/26/23 3. The TS-2 interviewed on August 29, 2023 at 1:53 PM acknowledged the laboratory failed to check of each batch of media for its ability to support and/or inhibit growth and failed to check each batch of media for sterility. 4. The number of patient tests performed using the media indicated above could not be determined at the time of the survey.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. 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 blood bank temperature charts and interview with the Technical Supervisor (TS-2), the laboratory failed to perform and document quarterly inspections of the audible alarm system for the refrigerator and the freezer used to store blood and blood product storage. Findings include: 1. The laboratory performs patient testing in the specialty of Immunohematology with a reported annual test volume of 603. It is the policy of the laboratory to perform a "quarterly alarm evaluation check" for the refrigerator and the freezer used to store blood and blood products. 2. No documentation was presented for review from January 1, 2022 through August 29, 2023 to indicate the laboratory performed and documented audible alarm checks on a quarterly basis for the refrigerator and freezer which are used by the laboratory to store blood and blood products. 3. The TS-2 interviewed on August 29, 2023 at 2:35 PM confirmed the laboratory failed to perform and document audible alarm checks on a quarterly basis during the time period indicated above.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Review of 2021 and 2022 instrument comparisons for testing performed in the specialty of chemistry and hematology and interview with the technical consultant (TC-2), the laboratory failed to perform instrument comparisons for two of two chemistry analyzers and two of two hematology analyzers. Findings: 1. The laboratory utilizes the DXH900 and Coulter Ac-T Diff II analyzers to perform patient testing under the specialty of Hematology. 2. The laboratory utilizes two separate AU480 chemistry analyzers to perform patient testing under the specialty of Chemistry. 3. No evidence was presented for review from 2021 and 2022 to indicate the laboratory evaluated and defined the relationship between test results for the hematology analyzers and chemistry analyzers listed above. 4. Interview with the TC-2 on August 29, 2023 at 12:45 PM confirmed the laboratory failed to perform instrument comparisons for the hematology and chemistry analyzers indicated above. 5. The laboratory results approximately 122,109 chemistry patient results and 50,034 hematology patient results annually.

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, analytic test records, laboratory policies and procedures and interview with the Technical Supervisor (TS-2), the laboratory's analytic QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified with quality control, maintenance and alarm checks, calibration verification procedures, and comparison of instrumentation procedures. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of Quality Control (QC) and sterility records for testing performed in the specialty of Microbiology. See D5477 for findings. 2. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of weekly maintenance performance for the chemistry analyzers used by the laboratory for patient testing. See D5429 for findings. 3. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of quarterly audible alarm checks for the refrigerator and freezer used to store blood and blood products. See D5555 for findings. 4. No QA documentation was presented for review during the survey to indicate the laboratory monitored, assessed and, when indicated, corrected problems identified with a lack of instrument comparison records for testing performed in the specialties of Chemistry and Hematology. See D5775 for findings. 5. The TS-2 interviewed on August 29, 2023 at 3:00 PM confirmed the laboratory's QA processes at the time of the survey were not effective at monitoring, identifying and correcting problems associated with the analytic laboratory systems as indicated above.

<p>D6049</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel competency records for individuals who perform Arterial Blood Gas (ABG) testing and interview with the technical consultant (TC-2), the procedures for evaluation of the competency of the staff failed to include a review of quality control records. Findings include: 1. Review of annual and 6-month competency records from 2022 and 2023 for five out of five testing personnel failed to include a review of quality control records. 2. The TC-2 interviewed on August 29, 2023 at 10:45 AM confirmed the procedures for the evaluation of competency of testing personnel who perform ABG testing failed to include a review of quality control records. 3. The laboratory began ABG testing on the Nova Prime Plus analyzer in August 2021.</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 the number and severity of deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing - Laboratory Director was not met. The laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H of this part (see D2016 and 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 information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a PT program for the regulated analyte, Digoxin. See D6076 for findings.</p>