Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 03D0706385	**(X3) Date Survey Completed** 05/20/2021
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**
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2019 and 2020 for testing performed by the laboratory and interview with the facility personnel, the laboratory director failed to sign the PT attestation statements. Findings include: 1. The laboratory performs testing in the specialties of Microbiology, Chemistry, Hematology, and Immunohematology, with an approximate annual test volume of 125,204. 2. The PT attestation statement presented for review for the first event of 2019 for Coagulation lacked the director's signature. 3. The PT attestation statements presented for review for the second events of 2019 for Chemistry, Comprehensive Chemistry and Endocrinology (serum hCG) lacked the director's signature. 4. The PT attestation statements presented for review for the first event of 2020 for Hematology (Blood Cell Identification) and the third event of 2020 for Urine Drug Screens lacked the director's signature. 5. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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.

	This STANDARD is not met as evidenced by: Based on lack of instrument printouts for patient test results generated from the Opti CCA-TS2 blood gas analyzer and interview with the testing personnel, the laboratory failed to retain patient test records for at least 2 years. Findings include: 1. The laboratory began patient testing using the Opti CCA-TS2 blood gas analyzer on July 9, 2020. 2. No documentation was presented for review during the survey conducted on May 20, 2021 to indicate the laboratory retained patient test records (instrument printouts) from the Opti CCA-TS2 blood gas analyzer for testing that occurred from July 9, 2020 through the date of the survey. 3. The testing personnel acknowledged that patient test records from the Opti CCA-TS2 analyzer as indicated above were not being retained for at least 2 years.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity and number of deficiencies cited for quality control practices identified during the survey conducted on May 20, 2021, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the specialties of Chemistry and Hematology. See D5401, D5421, D5437, D5445 and D5447 for findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of a written procedure manual for testing performed under the specialty of Chemistry and interview with the facility personnel, the laboratory failed to have a written procedure for performing Arterial Blood Gas (ABG) testing on the Opti CCA-TS2 analyzer. Findings include: 1. The laboratory began testing patient specimens on the Opti CCA-TS2 analyzer in July 2020. 2. No written, approved procedure manual was presented for review during the survey conducted on May 20, 2021 to indicate the laboratory had established procedures for testing performed on the Opti CCA-TS2 analyzer. 3. The facility personnel confirmed that the laboratory did not have an established written, approved procedure for the testing indicated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	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 the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of performance specification documentation of the Opti CCA-TS2 blood gas instrument that was acquired by the laboratory on July 9, 2020 and interview with the testing personnel, the laboratory failed to provide documentation indicating verification of performance characteristics for the instrument including accuracy, precision, reportable range and reference range. Findings include: 1. The laboratory acquired the Opti CCA-TS2 blood gas analyzer on July 9, 2020. 2. During the survey conducted on 5/20/21, no documentation was presented for review to indicate the laboratory verified the manufacturer's performance characteristics of the Opti CCA-TS2 blood gas analyzer including accuracy, precision, reportable range and reference range, prior to patient testing. 3. During the survey, the testing personnel confirmed that approximately 254 patient tests had been performed on the Opti CCA-TS2 blood gas analyzer from July 9, 2020 through the date of the survey. 4. The testing personnel interviewed on 5/20/21 at approximately 11:30am stated that the laboratory received the new Opti CCA-TS2 blood gas analyzer by mail shipment, unboxed it, plugged it in and began using it for patient testing. 5. The testing personnel confirmed that the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the Opti CCA-TS2 blood gas analyzer prior to patient testing.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration records for the AcT 5 Diff hematology analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory utilized the AcT 5 Diff hematology analyzer during 2019 to perform patient testing. The laboratory's approximate annual test volume in the specialty of Hematology is 34,740. 2. No documentation was presented for review during the survey conducted on May 20, 2021 to indicate the laboratory performed and documented calibration procedures

	every 6 months during 2018 and 2019 as required by the manufacturer for the analyzer indicated above. 3. The calibration records for the AcT 5 Diff analyzer reviewed during the survey indicated the laboratory performed a calibration on 5/16 /2018 and the calibration was not performed again until 11/26/19. 4. The facility personnel confirmed that the laboratory failed to perform a calibration every six months on the AcT 5 Diff analyzer during 2018 and 2019.
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 for review and interview with the facility personnel, (A) the laboratory failed to perform QC on the Medtox analyzer as required and (B) the laboratory failed to perform and document control procedures for Blood Gas testing using the number and frequency required by the laboratory. Findings include: A1. The laboratory utilizes the Medtox Urine Drug Screen analyzer for patient testing. The laboratory's approximate annual test volume in the sub-specialty of Toxicology is 1,096. A2. At the time of the survey conducted on May 20, 2021, the laboratory's procedure for QC on the Medtox analyzer consisted of performing an external QC material (positive and negative) monthly or prior to using each new lot of test devices. A3. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. A4. At the time of the survey it was determined that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test kit. A5. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the Medtox Urine Drug Screen Analyzer. A6. The number of patients tested during the time period indicated above could not be determined at the time of the survey. B1. The laboratory performs patient blood gas testing on the Opti CCA-TS2 analyzer under the specialty of Chemistry, with an approximate annual test volume of 888. B2. The laboratory policy titled, "Arterial Blood Gas Quality Assurance Policy" presented for review during the survey conducted on May 20, 2021 indicates the laboratory must perform one level of liquid Opti Check controls every eight hours on patient testing days (and through the night as needed). These will include alternating high and low levels". In addition, the laboratory performs a Standard Reference Cassette (SRC) control twice daily, at 7:00am and 3:00pm. The SRC control is one cassette containing 3 levels of control (high, normal and low). B3. The laboratory failed to perform one level of the Opti Check control every eight hours on patient testing days as evidenced by review of the laboratory's quality control records for 12/02/20. On 12 /02/20, the laboratory performed the Opti Check Level 3 control (Lot# 0379) at 07: 30am. No documentation of the Opti Check Level 1 control performance was

	presented for review for the remainder of the day on 12/02/20. B4. Approximately 2 patients were tested using the Opti CCA-TS2 blood gas analyzer on 12/02/20. B5. The facility personnel acknowledged that the laboratory failed to perform two levels of Opti Check controls on 12/02/20, as indicated above. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test reports, review of quality control (QC) policies and records for Thyroid Stimulating Hormone (TSH) testing performed on the Architect i-1000 analyzer and interview with the facility personnel, the laboratory failed to perform two control materials of different concentrations each day patient testing occurred. Findings include: 1. The laboratory performs patient testing in the sub-specialties of Routine Chemistry and Endocrinology, with an approximate annual test volume of 84,976. 2. The laboratory's policy titled, "Correct Quality Control Material" states, "Run Level 1 & 3 per day of use for the following analytes....TSH." 3. The QC documentation presented for review for TSH from the testing date of 2/01/2021 indicated the laboratory only performed the QC for Level 1 (performed at 11:46am). The laboratory failed to produce evidence that QC for Level 3 was performed on 2/01 /21. 4. The laboratory confirmed that one patient (patient# 4434018) was tested for TSH on 2/01/2021. 5. The facility personnel confirmed that the laboratory failed to successfully perform 2 levels of quality control for TSH, as indicated above, prior to reporting patients' test results on each date of patient testing.
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 laboratory personnel, the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified with quality control, establishment of performance verification, and calibration verification. 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) records for testing performed in the specialty of Chemistry. See D5445 (A) and (B) and D5447 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 verification of performance

	characteristics for the instrumentation used for blood gas testing. See D5421 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 calibration verification records for testing performed in the specialty of Hematology. See D5437 for findings. 4. The facility personnel confirmed that the laboratory's QA processes at the time of the survey conducted on May 20, 2021 were not effective at monitoring, identifying and correcting problems associated with the analytic laboratory systems.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test results maintained in the electronic health record (EHR) system, review of the laboratory form used to record patient test results and interview with the testing personnel, the laboratory failed to accurately report the Arterial Blood Gas (ABG) test result for one patient. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing, with an approximate annual test volume of 888. It is the practice of the laboratory to manually document the ABG test results onto the laboratory's 'Cardiopulmonary ABG Log' and then to manually enter the test results into the EHR (Electronic Health Record) for each patient tested. 2. Review of ABG test results for the analyte, $PaCO_2$, in the EHR for patient #4441037 performed on 4/25/21 at 11:32am indicated the test result for $PaCO_2$ as 45.5 mmHg, however the laboratory form used to record the test result indicated the $PaCO_2$ test result as 45.7 mmHg. 3. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the incorrect test result documented in the EHR for the patient indicated above. 4. The instrument printout showing the measured test results for the patient indicated above was not retained by the laboratory. See D3031 for findings. 5. The testing personnel confirmed that the laboratory failed to manually enter the correct test result in the EHR for the patient indicated above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as

	evidenced by: D6040 - failure to verify and establish test performance characteristics for the Opti CCA-TS 2 blood gas analyzer; D6042 - failure to ensure that a Quality Control program is maintained and failure to ensure that acceptable levels of analytic performance were maintained throughout the entire testing process; and D6055 - failure to evaluate and document the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on lack of test verification documentation for the Opti CCA-TS 2 blood gas analyzer put into use by the laboratory in July 2020, the technical consultant failed to perform and document the verification of test procedures performed and failed to verify the laboratory's test performance characteristics, including the precision and accuracy of each test and test system in the specialty of Chemistry. See D5421 for findings.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on lack of quality control records for testing performed on the Medtox Urine Drug Screen test, lack of quality control records for TSH testing performed on the Architect i-1000 analyzer and lack of quality control records for Blood Gas testing, the technical consultant failed to establish the parameters for acceptable levels of analytic performance and failed to ensure that these levels are maintained throughout the entire testing process. See D5445 and D5447 for findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of performance documentation for review, the technical consultant

	failed to reevaluate and document the performance of 3 out of 3 testing personnel responsible for moderate complexity testing performed on the Opti CCA-TS2 Blood Gas analyzer. Findings include: 1. The laboratory began using a new blood gas analyzer, Opti CCA-TS 2, in July 2020. 2. No performance documentation from July 2020 or thereafter was presented for review during the survey conducted on May 20, 2021 to indicate the technical consultant reevaluated and documented the performance of 3 out of 3 testing personnel responsible for moderate complexity testing on the new Opti CCA-TS2 analyzer implemented by the laboratory in July 2020. 3. The facility personnel confirmed that the technical consultant failed to reevaluate and document the performance of individuals responsible for performing patient testing on the Opti CCA-TS 2 after the instrument was put into use by the laboratory in July 2020.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with the facility personnel, the technical supervisor failed to evaluate and document the competency of one testing personnel in the main laboratory during 2019 and 2020. Findings include: 1. The annual competency assessment provided for review during the survey from 2019 and 2020 for one individual listed on the CMS-209, Laboratory Personnel Form as Technical Supervisor, Technical Consultant, General Supervisor and Testing Personnel was performed and approved by an individual who is not listed as laboratory personnel on the CMS-209, Laboratory Personnel Form. 2. The facility personnel confirmed that the individual who performed the competency evaluation was not affiliated with the laboratory and confirmed that laboratory did not have documentation of an approved competency assessment for the individual indicated above for 2019 and 2020.