Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0706385	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northern Cochise Community Hospital	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed in the specialty of Hematology, at least twice annually during 2016 and 2017. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on the Coulter HMX analyzer under the specialty of Hematology, with an approximate annual test volume of 35,750. It is the practice of the lab to perform a manual WBC differential if the sample meets the criteria as established in laboratory policy. 2. The laboratory is enrolled in proficiency testing (PT) for the automated WBC differential portion of the CBC, which it uses as the primary test method. 3. No documentation was presented for review during the survey conducted on July 24, 2018 to indicate the laboratory verified the accuracy of manual WBC differentials at least twice annually during 2016 and 2017. 4. The facility personnel confirmed that the laboratory failed to verify the accuracy of the manual WBC Differentials.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of coagulation test records, review of the manufacturer's package insert for coagulation reagents and interview with the facility personnel, the laboratory failed to use the correct International Sensitivity Index (ISI) value for each lot of thromboplastin reagent used on the analyzer. Findings include: 1. The laboratory performs patient testing on the ACL-Elite coagulation analyzer. The analyzer uses a reagent called "Recombiplastin 2G". 2. The ISI value contained in manufacturer's package insert from the Recombiplastin 2G reagent must be correctly programmed into the analyzer for each new lot of reagent used on the analyzer, to ensure the correct ISI value is used in the calculation of the International Normalized Ratio (INR). 3. Direct inspection of the Recombiplastin 2G reagent data entered into the analyzer at the time of the survey conducted on July 24, 2018 revealed the following: Lot# N0378719, expiration date 03/2019, ISI = 1.04. 4. Direct inspection of the manufacturer's package insert for the Recombiplastin reagent used on the analyzer at the time of the survey revealed the following information: Lot# N0285578, expiration date 02/2020, ISI = 1.01. 5. It is the practice of the laboratory to use a "Coagulation Worksheet" to document daily controls. The worksheet contains information specific to the Lot number, expiration date and ISI value for all reagents/controls currently used on the analyzer. The facility personnel stated that the information contained on the worksheet is updated by the laboratory whenever a new lot of control/reagent is put into use. 6. The Coagulation Worksheet presented for review during the survey failed to contain updated information with regard to the Recombiplastin 2G reagent, including lot#, expiration date and ISI value. 7. The testing personnel interviewed during the survey stated that a new lot of Recombiplastin (Lot# N0285578, exp. date 02/2020, ISI = 1.01) was put into use on the analyzer approximately in the beginning of July 2018, but the new lot information, including the ISI value, was not updated in the analyzer or on the Coagulation Worksheet. 8. The laboratory failed to document the exact date in which the Recombiplastin reagent (Lot# N0285578, exp. date 02 /2020, ISI = 1.01) was put into use for patient testing on the ACL-Elite analyzer. 9. The number of patients tested using the incorrect ISI value could not be determined at the time of the survey. 10. The facility personnel confirmed that the laboratory failed to update the ISI value in the analyzer for the current lot of Recombiplastin 2G reagent used at the time of the survey, failed to document the exact date the current lot of Recombiplastin 2G reagent was put into use for patient testing, and failed to update the Coagulation Worksheet with the current reagent information.
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 facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required. Findings include: 1. The laboratory performs

	serum hCG testing using a Quick Vue serum pregnancy test kit under the sub-specialty of Endocrinology, with an approximate annual test volume of 1,951. On the date of the survey, July 24, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, once each month and/or each new lot of test kit. 2. 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. 3. During the survey, review of QC records from 2016 through the date of the survey indicated the laboratory performed and documented QC with the number and frequency described above, and as of January 1, 2016, the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test kit. 4. 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 Quick Vue serum pregnancy test. 5. The number of patients tested during the time period indicated above could not be determined at the time of the survey.
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, review of the laboratory's QC procedures and interview with the facility personnel, 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. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Bacteriology, with an annual approximate test volume of 1,547. 2. The laboratory utilizes the following media for patient testing: TSA, CNA, MAC, CHOC, THIO and Martin-Lewis. 3. No QC documentation was presented for review on the day of the survey, July 24, 2018, to indicate the laboratory checked 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. 4. The facility personnel confirmed that the laboratory was performing a visual check of each batch of media but was not checking each batch of media for its ability to support and/or inhibit growth.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the testing personnel,

	the laboratory failed to document gram stains for positive and negative reactivity using control organisms each week of use. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Bacteriology with an approximate annual test volume of 1,547. It is the practice of the laboratory to perform gram stains on patient specimens if warranted, as outlined in laboratory policy. 2. During the survey conducted on July 24, 2018, review of the laboratory's Gram Stain Quality Control (QC) Log from 2017 indicated the laboratory last performed and documented the acceptability of the gram stain using a positive and negative organism on July 21, 2017. 3. The facility personnel confirmed that the laboratory failed to document the acceptability of the gram stain using a positive and negative organism since July 21, 2017. 4. The number of patient tested since that time could not be determined at the time of the survey.
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 and interview with the facility personnel, the laboratory failed to have written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory monitored or identified problems with analytic activities, including but not limited to, quality control procedures for the Quick Vue serum pregnancy test, See D5445 for findings; quality control procedures for the Gram Stain, see D5503 for findings; quality control procedures for media used in bacteriology testing, see D5477 for findings; and test system failures identified with Coagulation testing, see D5411 for findings. 2. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to monitor specific areas of the analytic systems as indicated above.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review quality assessment (QA) documentation and interview with the facility personnel, the laboratory failed to document a review of corrective actions taken to resolve problems identified throughout the laboratory. Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, Routine Chemistry, Hematology and Immunohematology, with an approximate annual test volume of 124,266. 2. The laboratory utilizes a "Quality Assurance Form" to

	document occurrences and corrective actions taken by laboratory personnel. The form includes an area for the general supervisor to sign and date indicating that the information has been reviewed and the corrective action/follow-up was complete and effective at resolving the issue. 3. The Quality Assurance Form presented for review during the survey for occurrences that took place from April 13, 2018 through the date of the survey on July 24, 2018 failed to include a signature/date of the general supervisor or any other laboratory personnel, indicating the occurrences and resulting corrective actions were reviewed. 4. The facility personnel confirmed that the Quality Assurance Form indicated above was not reviewed by laboratory personnel.
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: 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.
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: (A) Based on lack of quality control records for testing performed in the sub-specialty of Bacteriology, lack of quality control records for testing using the serum pregnancy test kit, and lack of quality control records for Gram Stain testing, the technical consultant failed to establish a quality control program appropriate for testing performed. See D5445, D5477 and D5503 for findings. (B) Based on errors identified during the survey for the Coagulation test system, the technical consultant failed to ensure that the parameters for acceptable levels of analytic performance are maintained throughout the entire testing process. See D5411 for findings.