Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0877461	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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the signature page for the policies and procedures pertaining to the Cardiopulmonary Department and interview with the facility personnel, the current and previous laboratory director failed to approve, sign and date the signatures page acknowledging the review and acceptability of the policies and procedures. Findings include: 1. The laboratory director currently listed in the CLIA federal system has been director since August 2, 2016 but his signature was not indicated on the signature page. 2. According to the facility personnel another physician has taken over the responsibilities of laboratory director as of March 2018. 3. HHS or its designee (The Arizona State Agency CLIA Program) was not notified of the new director within 30 days of the change in director as required under the CLIA regulations 493.51.
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 required as indicated under the QC regulations for routine chemistry 493.1267 (a)-(d). Findings include: 1. The laboratory performs patient blood gas testing on the Opti CCA-TS analyzer under the specialty of Chemistry, with an approximate annual test volume of 471. The laboratory performs Opti Check liquid controls every other month and three levels of the SRC electronic controls daily. 2. There was no evidence that the laboratory was performing the required frequency of liquid controls on a daily basis and no evidence that the laboratory had an established IQCP. 3. The manufacturer recommends level 1 and level 3 of the SRC electronic controls once daily and the Opti check liquid controls be run at 1 month intervals with each new shipment of cassettes. 4. The manufacturer's recommendations or any other QC modifications can only be followed once an IQCP is established. The manufacturer does supply a guide for implementation of an IQCP. 4. The facility personnel acknowledged that they were unaware of the specific requirements for quality control testing under the regulations. .
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 review of the quality control (QC) data the laboratory presented for review for the blood gas testing, the technical consultant failed to establish a quality control program for the testing performed under the sub-specialty of routine chemistry (see D5445 for findings).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of training and competency assessments for 2017 and 2018 pertaining to blood gas testing presented for review and interview with the facility personnel, the technical consultant failed to indicate by signature and date that any of the assessments performed on six out of six testing personnel were evaluated by the technical consultant indicated on the CMS-209 form (Laboratory Personnel Report). Findings include: 1. The competency assessment evaluations were being signed off by one of the testing personnel indicated on the CMS-209 form with no indication of competency assessment being performed by the technical consultant for moderate

	complexity testing under the specialty of Chemistry. 2. The technical consultant acknowledged that the competency assessments were being performed by the testing personnel.