Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0057925	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Little Colorado Medical Center	1501 N Williamson Avenue, Winslow, 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
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of hematology test records and interview with the laboratory personnel, the laboratory failed to document the background count that is performed each day of patient testing on the hematology analyzer. Findings include: 1. The laboratory performs patient testing on the Sysmex XS-1000i hematology analyzer, with an approximate annual test volume of 54,694. 2. During the survey conducted on 5/10/2018, it was the practice of the laboratory to perform the background count on the analyzer each day of patient testing and the results of the background count were stored on the analyzer. Due to the storage capacity of the analyzer, the background count documentation was not retained prior to 7/16/2017. 3 No other documentation was presented for review during the survey to indicate the laboratory performed and documented the background count prior to 7/16/2017 for each day of patient testing. 4. The laboratory personnel confirmed that the laboratory performed the background count each day prior to testing patients, however the laboratory did not have a system in place at the time of the survey to maintain the background count documentation for a period of two years as required.
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 Siemens EXL 200 chemistry analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory uses a Siemens EXL 200 analyzer to conduct patient testing in the specialty of Chemistry, with an approximate annual test volume of 140,328. 2. No documentation was presented for review for 2017 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. The laboratory provided documentation of a calibration verification performed on 8/16/2016 and 2/26 /2018, but no other documentation was presented for review. 3. The facility personnel confirmed that the laboratory did not perform a calibration verification every six months as required.
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 for testing performed on the: (A) Solana analyzer, (B) BioFire Film Array analyzer, (C) Cepheid Genexpert analyzer (D) Med-Tox analyzer and the (E) TLi-sys test system. Findings include: A1. The laboratory began

	patient testing on the Solana analyzer under the specialty of Microbiology in February 2017. The laboratory utilizes 3 separate test cartridges to test for C. Diff, Strep Group A Ag Screen and Strep Group C/G Ag Screen. On the date of the survey, May 10, 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. A2. 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 and no documentation was presented for review to indicate the laboratory performed and documented an Individualized Quality Control Plan (IQCP) for this test system. B1. The laboratory performs patient testing on the BioFire Film Array analyzer, including the Respiratory Panel. At the time of the survey the laboratory's QC procedure for the Respiratory Panel consisted of performing two levels of external control material, once each month and/or each new lot of test kit. B2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations for the Respiratory Panel, each day of patient testing as required and no documentation was presented for review to indicate the laboratory performed and documented an Individualized Quality Control Plan (IQCP) for this test. C1. The laboratory performs patient testing on the Cepheid Genexpert analyzer, including the MTB panel and the S. Aureus panel. At the time of the survey the laboratory's QC procedure for each panel consisted of performing two levels of external control material, once each month and/or each new lot of test kit. C2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations for the MTB and S. Aureus panels each day of patient testing as required and no documentation was presented for review to indicate the laboratory performed and documented an Individualized Quality Control Plan (IQCP) for these tests. D1. The laboratory performs patient testing on the Med-Tox analyzer under the sub-specialty of Toxicology. At the time of the survey the laboratory's QC procedure for testing consisted of performing two levels of external control material, once each month and/or each new lot of test kit. D2. 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 on the Med-Tox analyzer as required and no documentation was presented for review to indicate the laboratory performed and documented an Individualized Quality Control Plan (IQCP) for this test system. E1. The laboratory performs Fetal Fibronectin testing on the TLi-sys analyzer under the specialty of Chemistry. At the time of the survey the laboratory's QC procedure for testing consisted of performing two levels of external control material, once each month and /or each new lot of test kit. E2. 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 on the TLi-sys analyzer as required and no documentation was presented for review to indicate the laboratory performed and documented an Individualized Quality Control Plan (IQCP) for this test system. 3. 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 test systems indicated above. 5. The number of patients tested on each test system during the time periods indicated above could not be determined at the time of the survey.
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: Based on lack of test comparison results from 2016 and 2017 and interview with the facility personnel, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results using separate Microbiology and Chemistry instruments. Findings include: 1. The laboratory utilizes the following molecular instruments for testing performed in the specialty of Microbiology: Biofire Film Array, Solana, and Cepheid Genexpert . Each analyzer has two readers that interpret the test results. The two readers of each test system are used interchangably by the laboratory. 2. No documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the test results generated by either reader for each test system indicated above. 3. The laboratory utilizes two Siemens EXL 200 analyzers (A and B) that are used interchangably for Glucose testing. 4. No documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the glucose test results performed on analyzer A and B as indicated above. 5. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to evaluate and document a comparison of test results between the instruments mentioned above.
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 the laboratory's established policies, review of Immunohematology Quality Control (QC) records and interview with the facility personnel, the laboratory failed to follow written policies and procedures to perform and document QA activities related to the analytic systems. Findings include: 1. The laboratory's established policy titled, "Lab Manager Duties and Responsibilities" lists several duties including, but not limited to, "Review daily Quality Control log for correct documentation of out of control results" and "Monthly review of Patient surveys, QC, Preventative maintenance, Daily Temperature checks, Blood Bank log, Specimen labeling, Test Problem." 2. Review of Blood Bank QC records for January 2018 indicated the testing personnel performed and documented the daily QC on 01/03 /18, however the QC form used on that date was documented by the testing personnel as 01/03/17. 3. Review of Blood Bank QC records indicated the general supervisor performed and documented a review of the Blood Bank QC on 7/30/17 for QC records from 06/30/17 through 07/30/17. The next documented review of Blood Bank QC records occurred on 03/01/18 for QC records from January 6, 2018 through March 1, 2018. 4. No documentation was presented for review during the survey to indicate the laboratory identified the date error on the Blood Bank QC records from January 3,

	2018. 5. No documentation was presented for review during the survey to indicate the laboratory followed their established policy and reviewed the Blood Bank QC each day of patient testing and reviewed the Blood Bank log monthly as stated in the policy referenced above. 6. The facility personnel confirmed that the laboratory failed to follow established policies regarding the review of QC records for testing performed in Blood Bank.
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 D5445, D5775 and D5791 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 for a semi-annual competency evaluation for one testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing during the first year the individual tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one out of one testing personnel who was hired in January 2017. 2. The facility personnel confirmed that the laboratory failed to have documentation of a semi-annual competency evaluation for the testing personnel indicated above.