Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0057925	05/19/2021
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
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 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, Diagnostic Immunology, Chemistry, Hematology, Immunohematology and Pathology with an approximate annual test volume of 243,999. 2. The PT attestation statement presented for review for the second event of 2020 for Hematology/Coagulation lacked the director's signature. 3. The PT attestation statements presented for review for the first and second events of 2020 for Chemistry lacked the director's signature. 4. The PT attestation statement presented for review for the second event of 2020 for Microbiology lacked the director's signature. 5. The PT attestation statements presented for review for the third event of 2019 and third event of 2020 for Immunology/Immunohematology lacked the director's signature. 6. The PT attestation statements presented for review for the second event of 2019 and second event of 2020 for Chemistry (Miscellaneous) lacked the director's signature. 7. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from 2020 and interview with the facility personnel, the laboratory failed to document corrective action for unsatisfactory PT scores for the test, Body Fluid Crystal analysis. Findings include: 1. The laboratory participated in two PT events for the test, Body Fluid Crystals, during 2020. The laboratory received a score of 50% for the 1st testing event. 2. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of the unsatisfactory PT score indicated above. 3. The facility personnel confirmed that the laboratory failed to document corrective action for the unsatisfactory PT score referenced above.
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 in the specialties of Hematology and Chemistry. Findings include: 1. The laboratory performs ROM (Rupture of Membrane) testing on patient specimens using the ROM Plus test kit under the specialty of Chemistry, with an annual approximate test volume of 6. 2. The laboratory performs Fetal Fibronectin testing on patient specimens using the Adeza /TLI test kit under the specialty of Hematology, with an annual approximate test volume of 8. 3. On the date of the survey, May 19, 2021, review of the laboratory's quality control policy titled, "General Quality Control Guidelines" stated, "Qualitative testing quality control will include a positive and negative control monthly if IQCP is in place. Otherwise, a positive an negative control are run each day of patient testing." 4. No QC documentation was provided for review during the survey for either test, ROM and Fetal Fibronectin, to indicate the laboratory performed two levels of control material of different concentrations each day of patient testing as required since January 1, 2016. The laboratory had not established an Individualized Quality Control Plan (IQCP) for either test. 5. The facility personnel confirmed that the laboratory did not perform and document external controls each day of patient testing as required since January 1, 2016.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)

	(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 document the acceptability of staining materials used for patient testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology, with an approximate annual test volume of 2. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occurred on 08/15/2019. Approximately 1 patient was tested on that date. 3. The facility personnel confirmed that the laboratory failed to document the stain acceptability on the date 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: Based on lack of test comparison results from 2018, 2019 and 2020 and interview with the facility personnel, the laboratory failed to evaluate and define the relationship twice a year between test results using two separate Chemistry instruments. Findings include: 1. The laboratory utilizes two separate Siemens Dimension EXL 200 instruments to perform chemistry testing on patient specimens. The laboratory's approximate annual test volume in the specialty of Chemistry is 142,721. The laboratory distinguishes each analyzer as EXL A and EXL B. 2. No documentation was presented for review during the survey conducted on May 19, 2021 to indicate the laboratory evaluated and defined the relationship between test results generated from each EXL 200 chemistry analyzer twice a year during 2018, 2019 and 2020. 3. The facility personnel confirmed that the laboratory failed to evaluate and define the relationship between test results twice a year for results generated from the EXL 200 analyzers during the years indicated 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 Quality Assessment (QA) documentation, lack of Quality Control

	(QC) documentation, lack of test comparison documentation and interview with the facility personnel, the laboratory failed to identify errors found in the analytic systems. Findings include: 1. The laboratory performs a monthly review of all Quality Control records, maintenance logs and temperature records. 2. No QA documentation was presented for review to indicate the laboratory identified and corrected errors found with a lack of QC performance for Histopathology, Chemistry and Hematology testing. See D5445 and D5473 for findings. 3. No QA documentation was presented for review to indicate the laboratory identified and corrected errors found with missing test comparison activities for the EXL 200 analyzer. See D5775 for findings. 4. The facility personnel confirmed that the laboratory's established QA policies and procedures at the time of the survey failed to identify and correct errors found in the analytic systems as indicated above.
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 reports and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the laboratory's information system (LIS). Findings include: 1. The laboratory performs patient testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, Immnuohematology and Histopathology, with an approximate annual test volume of 243,999. It is the practice of the laboratory to manually enter test results into the LIS for the following tests: Mono, HIV, Serum hCG, Body Fluid analysis, Microscopic Urine analysis, ROM (Rupture of Membrane) Plus, Fetal Fibronectin 2, and Blood Gas testing performed on the I-stat analyzer. 2. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered into the LIS. 3. The facility personnel confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are manually entered by the testing personnel into the LIS.
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 records and interview with the facility personnel, the laboratory failed to document the competency evaluation of one testing personnel in 2019 and 2020. Findings include: 1. No 2019 and 2020 annual competency evaluation was presented for review for one out of one testing personnel. 2. The facility personnel confirmed the testing personnel indicated above was missing annual competency evaluations for 2019 and 2020.