Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0533657	12/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
White Mountain Regional Medical Center	118 S Mountain Ave, Springerville, 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 from 2019 and interview with the facility personnel, the laboratory director failed to sign the PT attestation statements for Hematology and Chemistry. Findings include: 1. The laboratory participates in PT for testing performed in the specialties of Hematology and Chemistry. The laboratory's approximate annual test volume for these specialties is 21,098. 2. The PT attestation statement presented for review for the second event of 2019 for Chemistry lacked the director's signature. 3. The PT attestation statement presented for review for the first event of 2019 for Hematology lacked the director's signature. 4. The facility personnel confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) results from 2019 for testing performed in the Specialties of Microbiology and Hematology and interview with the facility personnel, the laboratory failed to document a self evaluation for PT test results that were not graded by the PT organization and received an exception code of [6] =Educational Sample, [3]=See Data Summary or [11]=No Appropriate Peer Group. Findings include: 1. The laboratory received the following Performance Results from the PT organization for Microbiology testing (analyte/method) during the first testing event of 2019: A) CSF and Urine Culture Mic/Zone Diameter Value = Not Graded [3]; B) CSF Culture Susceptibility Interpretation = Not Graded [6]; and C) Educational Susceptibility = Not Graded [11]. 2. The laboratory received the following Performance Results from the PT organization for Hematology testing (analyte/method) during the first event of 2019: Educational Blood Cell Identification = Not Graded [6]. 3. No written documentation was presented for review to indicate the laboratory evaluated the reported results against the expected results for the PT tests which were given the exception codes as indicated above. 4. The facility personnel acknowledged that there was no documented self evaluation for PT results that received exception codes.
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 lack of Quality Assessment (QA) documentation, review of Proficiency Testing (PT) records, lack of employee competency records and interview with the facility personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems. Findings include: 1. During the previous survey conducted on December 6, 2017 the laboratory was cited for a lack of established QA policies and procedures. The laboratory's response to the deficiency stated, "The laboratory manager will address any and all actions the laboratory took to determine why PT failures occurred, what steps were taken to correct areas found to be of concern and whether or not patient results tested for the failed analytes were evaluated to determine if the causes of the failed PT also affected patient results." 2. No QA documentation was presented for review during the survey conducted on December 19, 2019 to indicate the laboratory performed and documented QA activities as indicated in policy in order to identify and correct errors associated with unacceptable PT results. See D5293 for findings. 3. During the previous survey conducted on December 6, 2017 the laboratory was cited for a lack of annual competency records for laboratory employees. The laboratory's response to the deficiency stated, "...Annual reviews will be conducted after that for all personnel... The laboratory Manager will maintain a folder for each employee containing a competency evaluation test authorization form." 4. No documentation was presented for review during the survey conducted on December 19, 2019 to indicate the laboratory performed and documented QA activities to identify and correct errors associated with missing and/or unacceptable employee competency records. See D6128 for findings. 5. The facility personnel confirmed that the laboratory's QA processes at the time of the survey conducted on 12/19/2019 were not effective at

	monitoring, identifying and correcting problems associated with the general laboratory systems.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory's QA review failed to identify and correct problems found within the laboratory. Findings include: 1. The laboratory performs PT for the non-regulated tests D-Dimer and Vaginal Wet Preparation, as a means to verify accuracy for these tests which are not included in Subpart I and received unacceptable scores for the 1st testing event of 2019. The D-Dimer PT included 5 samples, all of which resulted in unacceptable scores and the Vaginal Wet Preparation included one sample which was scored as unacceptable. 2. No corrective action documentation was presented for review during the survey to indicate the laboratory resolved the problem of the unacceptable PT scores indicated above. 3. The facility personnel confirmed that the laboratory did not document corrective action for the unsatisfactory PT scores indicated above.
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, including repeat deficiencies, cited for quality control practices identified during the survey conducted on December 19, 2019, 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 Microbiology, Hematology and Chemistry. See D5439, D5445, D5477, D5543 and D5775 for findings.
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 Vitros 5600 chemistry analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration verification procedures as required during 2018 and 2019. **Findings include: 1. The laboratory uses a Vitros 5600 analyzer to conduct patient testing in the specialties of Diagnostic Immunology and Routine Chemistry, with an approximate annual test volume of 14,815. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification at least once every six months during 2018 and 2019, 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. 3. The facility personnel confirmed that the laboratory did not perform a calibration verification every six months as required. ** - This is a repeat deficiency from the previous survey conducted on 12/06/2017.
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 specialty of Microbiology. Findings include: 1. The laboratory performs C. Difficile (C Diff) testing on patient specimens using the Alere C Diff Quik Chek Complete test kit under the specialty of Microbiology. On the date of the survey, December 19, 2019, the laboratory's quality control procedure consisted of performing two levels of external control material, each new shipment. 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 C Diff QC records indicated the laboratory performed and documented QC with the number and frequency described above (see #1), and as of January 1, 2016, the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test system. 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 Alere C Diff test kit. 5. Approximately 79 patients were tested in 2019 using the C Diff test kit.
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 review of Quality Control (QC) documentation for Microbiology plated media and interview with the facility personnel, the laboratory failed to check each batch of media for sterility. Findings include: 1. The laboratory performs culture and sensitivity testing under the sub-specialty of bacteriology, with an approximate annual test volume of 1,412. 2. No documentation was presented for review to indicate the laboratory performed and documented sterility checks for the media used to perform culture testing on patient specimens. The laboratory last documented sterility checks on media in February 2018. 3. The facility personnel confirmed that the laboratory failed to perform sterility checks on each batch of media used for culture testing since February 2018.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory test records for Body Fluid testing and interview with the facility personnel, (A) the laboratory failed to perform at least one control material each day of testing and (B) it was determined that the laboratory failed to consistently perform and document duplicate cell counts using a hemacytometer. Findings include: 1. The laboratory performs body fluid counts using a hemacytometer, with an approximate annual test volume of 8. It is the practice of the laboratory to perform the count in duplicate for each patient specimen and it is the practice of the laboratory to

	perform 2 levels of Quality Control (QC) material with each patient specimen. A1. No QC documentation was presented for review from 2018 and 2019 to indicate the laboratory performed QC as indicated above and in laboratory policy. A2. The facility personnel confirmed that the laboratory failed to perform and document 2 levels of QC for body fluid testing. The last documented QC performed was in 2017. B1. Review of the 2018 and 2019 worksheets used to record body fluid count information indicated that the laboratory failed to consistently perform the manual cell count on body fluid specimens in duplicate. B2. The testing personnel confirmed that laboratory failed to consistently perform and document duplicate cell counts.
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 and 2019 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 two separate Cell-Dyn Ruby hematology instruments. **Findings include: 1. The laboratory utilizes two separate Cell-Dyn Ruby instruments to perform complete blood count (CBC) testing on patient specimens. The laboratory's approximate annual test volume in the specialty of Hematology is 6,283. 2. During the previous survey conducted on December 6, 2017 the laboratory was cited for the failure to have a system in place to evaluate and define the relationship between test results using the two separate hematology analyzers. The laboratory's response to the deficiency stated, "The laboratory will perform a comparison study for the two Cell-Dyn Ruby instruments located in Hematology. The comparison will include at a minimum of ten samples run and a percent difference between the two analyzers." 3. No 2018 and 2019 documentation was presented for review during the survey conducted on December 19, 2019 to indicate the laboratory implemented the above Plan of Correction and had a system in place that twice a year evaluates and defines the relationship between the test results from each Cell-Dyn Ruby instrument. 4. 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 two Cell-Dyn Ruby instruments. ** - This is a repeat deficiency from the previous survey conducted on 12 /06/2017.
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, calibration verification and comparison of test results. 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 specialties of Microbiology and Hematology. See D5445, D5477 and D5543 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 calibration verification records for testing performed in the specialty of Chemistry. See D5439 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 test comparison documentation for testing performed in the specialty of Hematology. See D5775 for findings. 4. The facility personnel confirmed that the laboratory's QA processes at the time of the survey conducted on 12/19/2019 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 reports and interview with the facility personnel, the blood gas laboratory failed to have a system in place to ensure the accuracy of test results that are electronically interfaced into the laboratory's information system (LIS). Findings include: 1. The blood gas laboratory performs testing on patient specimens on the ABL80 analyzer. The test results automatically interface from the analyzer to the LIS. 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 interfaced from the analyzer to 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 electronically sent from the analyzer to the LIS.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: The Condition of Laboratory Director is not met as evidenced by: D6092 - failure to ensure an approved corrective action plan is followed for unsatisfactory, unsuccessful and ungraded PT results; D6093 - failure to ensure that the laboratory maintains quality control programs to assure quality results, and D6094 - failure to maintain a quality assessment program to identify and correct errors as they occur.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on lack of corrective action documentation for review for unsatisfactory and ungraded proficiency testing (PT) results, the laboratory director failed to ensure that the laboratory follows an approved corrective action plan for unsatisfactory, unacceptable and/or ungraded PT results. See D5215 and D5293 for findings.
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 lack of quality control records and review of 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, D5477 and D5543 for findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 lack of quality assessment (QA) documentation, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5293 and D5791 for findings.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in

	accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of repeat deficiencies, the Condition of Technical Supervisor is not met as evidenced by: D6128 - the Technical Supervisor failed to perform and document annual competency evaluations for testing personnel.
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 evaluations for four out of six testing personnel in the main laboratory during 2018 and for one out of six testing personnel in the main laboratory during 2019. **Findings include: 1. The main laboratory provided no documentation for annual competency assessment for 2018 for three out of six testing personnel who performed patient testing for over one year. 2. The competency assessment provided for review for one general supervisor/testing personnel for 2018 was performed and approved by an individual who is not listed as laboratory personnel. 3. The main laboratory provided no documentation for annual competency assessment for 2019 for one out of six testing personnel who performed patient testing for over one year. 4. The facility personnel confirmed that the laboratory did not have documentation for competency assessment for the testing personnel indicated above for 2018 and 2019. ** This is a repeat deficiency from the previous surveys conducted on 11/05/2013, 11/05/2015 and 12/06/17.