Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0533657	03/29/2023
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2021 and 2022 sent to the State Agency by the PT provider, the laboratory failed to successfully participate in a PT program for the regulated analyte, PCO2 (Blood Gas) under the subspecialty of Routine Chemistry, resulting in subsequent unsuccessful PT performance. Findings include: 1. The laboratory's PT performance was unsatisfactory for the second event of 2021 for the regulated analyte, PCO2 (Blood Gas), with a score of 60%. 2. The laboratory's PT performance was unsatisfactory for the third event of 2021 for the regulated analyte, PCO2 (Blood Gas), with a score of 60%. 3. The laboratory's PT performance was unsatisfactory for the first event of 2022 for the regulated analyte,

	PCO2 (Blood Gas), with a score of 60%. 4. *Unsatisfactory participation in the second and third event of 2021 (two consecutive testing events) for the regulated analyte, PCO2 (Blood Gas), constitutes an initial unsuccessful PT performance. 5. **Unsatisfactory participation in the third event of 2021 and first event of 2022 (two consecutive testing events) for the regulated analyte, PCO2, constitutes an unsuccessful PT performance and a subsequent unsuccessful PT to the initial unsuccessful PT as outlined above in #4.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the regulated analyte, PCO2 (Blood Gas), for the second and third event of 2021 and first event of 2022 resulting in subsequent unsuccessful PT performance. See D2016 for findings.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) reports for 2021 sent to the State Agency by the PT provider and interview with the General Supervisor, the laboratory failed to attain a score of at least 100 percent of acceptable responses for each analyte/test in each testing event for testing performed under the specialty of Immunohematology. Findings include: 1. The laboratory's PT performance was unsatisfactory for the third event of 2021 for the regulated analytes, ABO group, D(Rho) typing, Unexpected antibody detection, and Compatibility testing, with a score of 0% for each analyte or test. 2. The general supervisor interviewed on March 29, 2023 at 11:50am acknowledged the unsatisfactory PT score of 0% for each analyte/test indicated above. 3. The laboratory's approximate annual test volume in the specialty of Immunohematology is 873.
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 accuracy verification documentation for review and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of testing

	performed under the specialty of Hematology at least twice annually. Findings include: 1. The laboratory began performing the test, Body Fluid Analysis - Crystal Exam, on March 17, 2022. 2. No documentation was presented for review during the survey conducted on March 29, 2023 to indicate the laboratory verified the accuracy of Body Fluid Crystal examinations at least twice annually from March 2022 through March 2023. 3. The GS interviewed on March 29, 2023 at approximately 12:20pm confirmed that the laboratory failed to verify the accuracy of the testing indicated above at least twice annually from March 2022 through March 2023.
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 written Quality Assessment policies and procedures for review and interview with the General Supervisor (GS), the laboratory failed to establish policies and procedures related to accuracy verification for Body Fluid - Crystal Examination testing. Findings include: 1. The laboratory began performing the test, Body Fluid Analysis - Crystal Exam, on March 17, 2022, under the specialty of Hematology. 2. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures related to the verification of accuracy process for the testing indicated above. 3. The GS interviewed on March 29, 2023 at approximately 12:25pm confirmed that the laboratory failed to have an established written policy specific to the verification of accuracy process for Body Fluid Analysis - Crystal Exam performed by the laboratory.
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 General Supervisor (GS), the laboratory failed to perform and document calibration verification procedures at least once every 6 months during 2021 and 2022. **Findings include: 1. The laboratory uses the Vitros 5600 analyzer to conduct patient testing in the specialty of Chemistry, with an approximate annual test volume of 128,040. 2. No documentation was presented for review to indicate the laboratory performed a calibration verification at least once every six months during 2021 and 2022, 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. Calibration verification record review revealed the laboratory performed calibration verification on February 16, 2021 and not again until August 19, 2022. 4. The GS interviewed on March 29, 2023 at 2:05pm confirmed that the laboratory failed to perform a calibration verification every six months on the Vitros 5600 as required. ** - This is a repeat deficiency from the previous surveys conducted on 12/06/2017 and 12/19/2019.
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 General Supervisor (GS), the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Hematology and subspecialty of Toxicology. Findings include: 1. The laboratory performs D-Dimer testing on patient specimens using the Alere Triage Meter Pro analyzer under the specialty of Hematology. 2. The laboratory performs Urine Drug Screen testing on patient specimens using the MedTox analyzer under the subspecialty of Toxicology. 3. On the date of the survey, March 29, 2023, review of the laboratory's quality control policies for each test referenced above indicated it is the practice of the laboratory to perform two levels of external QC material monthly or with each new lot. 4. No QC documentation was provided for review during the survey for either test, D-Dimer and Urine Drug Screen, to indicate the laboratory performed two levels of control material of different concentrations each day of patient testing during 2021 through the date of the survey. On the date of the survey, the laboratory had not established an Individualized Quality Control Plan (IQCP) for either test. 5. The GS interviewed on March 29, 2023 at 1:50pm confirmed that the laboratory failed to perform and document two levels of external control material each day of patient testing. The GS stated that approximately 40 patients are tested each month on the Alere Triage Meter Pro analyzer and approximately 35 patients are tested each month on the MedTox analyzer.

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 for BACT/ALERT culture media and interview with the general supervisor, the laboratory failed to check each batch of media for sterility and failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms. Findings include: 1. The laboratory uses the BacT Alert 3D/60 test system and culture media for blood culture incubation and preliminary identification. 2. No documentation was presented for review during the survey to indicate the laboratory performed and documented sterility checks for each batch of BacT Alert blood culture media used for testing patient specimens. 3. No documentation was presented for review during the survey to indicate the laboratory checked each batch of BacT Alert blood culture media for its ability to support growth and, as appropriate, select or inhibit specific organisms. 4. The general supervisor interviewed on March 29, 2023 at 2:35pm confirmed the laboratory failed to perform sterility checks and QC procedures as indicated above on each batch of BacT Alert blood culture media. 5. The laboratory's approximate annual test volume in the sub-specialty of Bacteriology is 2,403.
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) policies and procedures, analytic test records, and interview with the general supervisor, the laboratory's established QA policies and procedures failed to monitor, assess and, when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. 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 sub-specialties of Bacteriology, Hematology and Toxicology. See D5445 and D5477 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 performance for testing performed in the specialty of Chemistry. See D5439 for findings. 3. The general

	supervisor interviewed on March 29, 2023 at 3:30pm confirmed that the laboratory's QA processes were not effective at monitoring, identifying and correcting problems associated with the analytic systems.
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 lack of quality control records for Urine Durg Screen testing performed on the MedTox analyzer, lack of quality control records for D-Dimer testing performed on the Alere Triage Meter Pro analyzer and lack of quality control records for the media used in Blood Culture testing, the technical consultant failed to establish a quality control program appropriate for the testing performed and failed to establish the parameters for acceptable levels of analytic performance to ensure that these levels are maintained throughout the entire testing process. See D5445 and D5477 for findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 performance evaluation documentation and interview with the General Supervisor (GS), the technical consultant failed to evaluate and document the performance of seven testing personnel, at least semiannually during the first year the individual tested patient specimens on the BioFire Torch analyzer. Findings include: 1. No semiannual competency evaluation documentation specific to the BioFire analyzer was presented for review for seven out of seven testing personnel who began patient testing in July 2022. 2. The GS interviewed on March 29, 2023 at 11:20am confirmed that the technical consultant failed to perform and document semiannual competency evaluations for seven testing personnel who perform patient testing on the BioFire analyzer. 3. The laboratory began patient testing on the BioFire analyzer in July 2022. The tests performed include Blood Culture ID, GI panel and Respiratory panel.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on lack of competency evaluation documentation for review and interview with the General Supervisor (GS), the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing performed on the Medtox analyzer at least annually. Findings include: 1. During the survey conducted on March 29, 2023, no 2022 annual competency evaluation documentation (specific to urine drug testing performed on the Medtox analyzer) was presented for review for seven out of seven testing personnel. 2. The GS interviewed on March 29, 2023 at 11:17am confirmed the laboratory failed to provide documentation of annual competency evaluations from 2022 for the seven testing personnel indicated above for testing performed on the Medtox analyzer.
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 was found to be not met based on the failure to provide overall management and direction as evidenced by D6089 - ensuring that proficiency testing samples are tested as required under Subpart H..
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, it was determined that the laboratory director failed to ensure that PT samples are tested in a manner that results in successful participation in a proficiency testing program for the regulated analyte, PCO2 (Blood Gas), as required under Subpart H. See D2016 for findings.