Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 03D2192900	**(X3) Date Survey Completed** 07/25/2023
Name of Provider or Supplier Fountain Hills Medical Center, Llc	**Street Address, City, State** 9700 N Saguaro Blvd, Fountain Hills, 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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2021, 2022, and the 1st Event of 2023, and an interview with the Technical Consultant (TC-1) the lab failed to enroll in an HHS approved PT program for regulated testing performed in the specialties of Hematology and Chemistry, which are included in subpart I. Findings include: 1. No documentation was presented for review during the survey conducted on 7/25/23 to indicate the laboratory was enrolled during 2021, 2022, and the 1st Event of 2023 in a CMS-approved PT program for regulated analytes included in subpart I in the specialities of Hematology and Chemistry. 2. The laboratory performs testing for the following regulated analytes: White Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, Platelets, White Blood Cell Differential, Albumin, Chloride, Calcium, Glucose, Magnesium, Potassium, Sodium, total Carbon Dioxide (tCO2), blood urea nitrogen (BUN), and Creatinine. 3. The TC-1 interviwed on 7/23/23 at 10:00 AM. confirmed the laboratory was not enrolled in a CMS-approved PT program in 2021, 2022, and the 1st Event of 2023 in the specialities of Hematology and Chemistry. 4. The annual reported test volume is 30,000 tests in the specialty of Hematology and 35,000 tests in the specialty of Chemistry.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the Technical Consultant competency assessment and interview with the Technical Consultant (TC-1), the laboratory failed to follow established policies and procedures to assess the competency of the Technical Consultant. Findings include: 1. The CMS-209 Laboratory Personnel form presented for review during the survey listed two (2) Technical Consultants, TC-1 and TC-2. 2. The 'Technical Consultant Competency Assessment and Skills Verification' form reviewed for TC-2 completed on 5/01/21 failed to include assessment of ensuring the laboratory is enrolled in a HHS approved proficiency testing program. 3. No documentation was presented for review to indicate the laboratory assessed the competency of TC-1. The TC-1 has been listed as Technical Consultant since April 2023. 4. The TC-1 interviewed during the survey at 10:15 AM on 07/25/2023 confirmed the laboratory failed to follow established personnel competency policies to assess the competency of TC-1 and the competency assessment performed for TC-2 failed to include assessment of ensuring the laboratory is enrolled in a HHS approved proficiency testing program. 5. The laboratory began patient testing on 04/05/2021 in the specialties of Chemistry and Hematology, with an approximate annual test volume of 65,000.
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 Technical Consultant (TC-1), the laboratory failed to verify the accuracy of analytes not included in subpart I at least twice annually during 2021 and 2022. Findings include: 1. No documentation was presented for review during the survey conducted on July 25, 2023 to indicate the laboratory verified the accuracy of D-Dimer, Troponin I, Lactate and Phosphorus testing at least twice annually during 2021 and 2022. 2. The TC-1 interviewed on July 25, 2023 at 10:05 AM confirmed the laboratory failed to verify the accuracy of the analytes indicated above at least twice annually during 2021 and 2022. 3. The laboratory reports an annual test volume of 65,000.
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 established Quality Assessment (QA) policies and procedures and interview with the Technical Consultant (TC-1), the laboratory's established QA policies and procedures failed to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: 1. The laboratory's established QA form titled 'Monthly Quality Assessment Checklist' includes a section on Proficiency Testing Polices. The form list two items to monitor under Proficiency Testing Policies including, "Proficiency tests were handled in the same manner as patient specimens" and "Proficiency tests were evaluated, failures were investigated and remedial action was taken and documented." The form provides a space for the laboratory to document "Yes/No/NA" for each item. 2. Review of the Monthly Quality Assessment Checklist from April 2023 indicated the laboratory marked "yes" to each Proficiency testing item that is monitored by the laboratory. 3. The laboratory's QA process failed to identify and correct problems associated with the lack of Proficiency Testing (PT) enrollment. See D2000 for specific findings. 4. The TC-1 interviewed on 07/25.2023 at 12:50 PM confirmed the laboratory's Quality Assessment process and procedures failed to effectively identify and correct problems associated with non-enrollment in Proficiency testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct inspection of three levels of Sysmex Quality Control (QC) vials and interview with the Technical Consultant (TC-1), the laboratory failed to label the Sysmex QC vials with the correct open expiration date. Findings include: 1. The laboratory began patient testing using the Sysmex XP-300 analyzer on 4/5/2021, with continued use through the date of the survey performed on 07/25/2023. 2. Review of the laboratory's established policy and test manufacturer's package insert indicates Sysmex QC material has an open expiration date of 14 days. 3. Direct inspection of the Sysmex QC vials (QC lot numbers: Level 1 - 31650710, Level 2 - 31650711, Level 3 - 31650712) used by the laboratory at the time of the survey revealed a hand-written open date of 07/25/23 and hand-written expiration date of 09/20/2023. 4. The laboratory failed to label the QC vials indicated above with the correct open expiration date. 5. The TC-1 interviewed on 07/25/23 at 12:10 PM confirmed the laboratory failed to document the correct expiration date on the Sysmex QC vials that were in use on the date of the survey. 6. The laboratory's approximate annual test volume in the specialty of Hematology is 30,000.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of maintenance logs for the Pathfast Analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to document the weekly maintenance as required by the manufacturer. Findings include: 1. The laboratory failed to document weekly maintenance on the Pathfast for one out of four weeks in February 2023, one out of four weeks in March 2023, and one out of four weeks in April 2023. 2. The weekly maintenance includes: Replace Tip Waste Box, Clean Reagent Cartridge Rack, and Clean Stage Surfaces. 3. On 7/25/2023 at 1:00 PM, the TC-1 interviewed acknowledged the maintenance activities listed above were not performed and documented for the weeks listed above.
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 Pathfast analyzer and interview with the Technical Consultant (TC-1), the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory uses the Pathfast analyzer to perform D-Dimer and Troponin I testing in the specialty of Chemistry. 2. No documentation was presented for review for the Pathfast analyzer from April 2021 through July 2023 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. 3. Records reviewed for the Pathfast indicated calibration verifications were performed on 02/18 /2021, 02/01/2022, and 06/21/2023. 4. The TC-1 interviewed on 07/25/2023 at 12:40 PM confirmed the laboratory failed to perform calibration verification activities on the Pathfast analyzer 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 Technical Consultant (TC-1), the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Chemistry. Findings include: 1. The laboratory performs testing using the Metlac-12 panel on the Piccolo Xpress analyzer under the specialty of Chemistry. Analytes on the Metlac-12 panel include: Lactate, Magnesium, Albumin, Chloride Glucose, Potassium, tCO2, Calcium, Creatinine, Phosphorus, Sodium and Blood Urea Nitrogen. 2. The laboratory performs D-Dimer and Troponin I testing using the Pathfast analyzer. 3. The laboratory failed to perform two levels of external quality control each day of patient testing for testing performed on the Piccolo analyzer and the Pathfast analyzer from April 5, 2021 through the date of the survey, July 25, 2023. 4. On the date of the survey, the laboratory had not established an Individualized Quality Control Plan (IQCP) for testing performed on the Pathfast analyzer and Piccolo Xpress analyzer. 5. The TC-1 interviewed on 07/25/2023 at 12:10 PM confirmed the laboratory failed to perform and document two levels of external control material each day of patient testing and had not created an IQCP for either test system listed above. 6. The number of patients affected could not be determined at the time of the survey. The reported annual test volume in the speciality of Chemistry is 35,000.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The Condition of Technical Consultant was found to be not met based on the failure of the Technical Consultant to provide technical oversight as evidenced by: D6041 - failure to ensure the laboratory was enrolled and participated in an HHS approved Proficiency Testing program for regulated analytes included in subpart I; D6042 - failure 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: D6051 - failure to ensure the procedures for evaluation of the competency of the staff include,

	but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and D6054 - failure to evaluate annual competency for testing personnel.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for 2021, 2022, and the first event of 2023, for the specialties of Chemistry and Hematology, the technical consultant failed to ensure the laboratory was enrolled and participated in an HHS approved PT program. See D2000 for findings.
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 D-Dimer and Troponin I testing performed on the Pathfast analyzer and lack of quality control records for MetLac-12 testing performed on the Piccolo Xpress analyzer, 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 for findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel competency records and interview with the technical consultant (TC-1), the procedures for evaluation of the competency of the testing personnel failed to include the assessment of test performance through testing external proficiency testing samples. Findings include: 1. Review of annual competency records from 2021 and 2022 for two out of two testing personnel failed to include the assessment of test performance through testing external proficiency testing samples. 2. The TC-1 interviewed on July 25, 2023 at 11:40 AM confirmed the

	procedures for the evaluation of competency of testing personnel failed to include the assessment of test performance through testing external proficiency testing samples.
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 Technical Consultant (TC-1), the technical consultant failed to evaluate and document the performance of one out of two individuals responsible for moderate complexity testing at least annually. Findings include: 1. No annual competency evaluation documentation from 2023 was presented for review for one out of two testing personnel (TP-4)who began patient testing on the Pathfast analyzer in April 2021. 2. The TC-1 interviewed on July 25, 2023 at 11:55 AM confirmed the technical consultant failed to evaluate and document the performance of TP-4 at least annually, who is responsible for moderate complexity testing on the Pathfast analyzer.