Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0707089	01/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Five Valleys Urology	2875 Tina Avenue Suite 101, Missoula, MT	

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
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 a record review of endocrinology, the manufacturer's instructions, and the laboratory's policy and procedure, the laboratory failed to include in their procedures a course of action to take if a test system becomes inoperable; a quality control procedure that includes the number and frequency of testing controls, criteria of acceptability, and the corrective action to take when control results fail to meet the laboratory criteria of acceptability (refer to D5403); failed to monitor the humidity as required by the Access 2 Immunoassay System manual (refer to D5413); failed to label the quality control material with lot number, product expiration date, reconstituted expiration date, and date in use (refer to D5415) and failed to ensure immunoassay quality control (QC) material were not used past their expiration date per the manufacturer's instructions (refer to D5417).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic

	examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of procedures, the manufacturer's product insert, and an interview with laboratory director (LD#1), the laboratory failed to include in their procedures a course of action to take if a test system becomes inoperable; a quality control procedure that includes the number and frequency of testing controls, criteria of acceptability, and the corrective action to take when control results fail to meet the laboratory criteria of acceptability from January 13, 2023, to January 13, 2025. Findings: 1. A review of "Policy/Procedures LAB 10.01" failed to include instruction for the number and frequency of testing controls, criteria of acceptability, and the corrective action to take when control results fail to meet the laboratory criteria of acceptability. 2. A review of the laboratory's Policy & Procedure Manual lacked a procedure for the course of action to take in case a test system becomes inoperable, including instrument failure, interface failure, and electronic information systems. 3. An interview with the LD #1 on January 13, 2025, at 2:26 PM, confirmed the laboratory's policy and procedure failed to include elements in their quality control to include the number and frequency of testing controls, criteria of acceptability, corrective action to take when control results failed to meet the laboratory criteria of acceptability, and the course of action to take if a test system becomes inoperable from January 13, 2023, to January 13, 2025.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of records, and interview with the laboratory director (LD #1), the laboratory failed to monitor the humidity as required by the Access 2 Immunoassay System manual from January 13, 2023, to January 13, 2025. Findings:

	1. On January 13, 2025, at 11:45 AM, observed one out of one Access 2 Immunoassay System in the laboratory. 2. A review of the Access 2 Reference Manual revealed the laboratory failed to ensure the environmental operational humidity was between 20% to 80% to operate properly. 3. No records to monitor the laboratory's humidity were available for review. 4. An interview with LD #1 on January 13, 2025, at 11:50 AM confirmed laboratory staff were not monitoring the humidity as required by the manufacturer's instructions from January 13, 2023, to January 13, 2025.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, the manufacturer's product insert, and an interview with the testing personnel (TP #1), the laboratory failed to label the quality control material with the lot number, product expiration date, reconstituted expiration date, and date in use from January 13, 2023, to January 13, 2025. Findings: 1. Observed on January 13, 2025, at 12:35 PM, three glass test tubes of aliquoted quality control in use in the refrigerator and several glass test tubes stored in the freezer. Test tubes' labels lacked lot number, product expiration date, reconstituted expiration date and date in use (thawed). 2. A review of Lyphochek Immunoassay Plus Controls product insert revealed the laboratory failed to label the test tubes with the manufacturer's reconstituted expiration date based on the temperature storage requirements. 3. Interview with TP#1 on January 13, 2025, at 12:40 PM, confirmed the QC test tubes are reconstituted Lyphochek Immunoassay Plus QC and the test tubes' labels lacked the lot number, product expiration date, reconstituted expiration date and date in use (thawed).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, the manufacturer's product insert, and interviews with testing personnel (TP) #1 and laboratory director (LD) #1, the laboratory staff failed to ensure immunoassay quality control (QC) materials were not used past their expiration date per the manufacturer's instructions for 159 out of 159 prostate-specific antigen (PSA) and 10 out of 10 testosterone tests performed on the Beckman Coulter Access 2 Immunoassay System from December 11, 2024, to January 13, 2025. Findings: 1. Observed on January 13, 2025, at 12:35 PM, test tubes of aliquoted quality controls were stored in the freezer and refrigerator with a reconstituted date of 11/21/2024. 2. Interview with TP#1 on January 13, 2025, at 12:40 PM, confirmed the test tubes were

	aliquots of Lyphochek Immunoassay Plus QC reconstituted on 11/21/2024 and stored long term in the freezer until needed for use, thawed and then stored in the refrigerator. 3. A review of the Lyphochek Immunoassay Plus Controls product insert revealed the laboratory failed to ensure reconstituted QC products that are frozen are not used after 20 days, and once thawed, any remaining material should be discarded. For reconstituted QC products that are then refrigerated, QC is not used after 3 days for PSA and 7 days for testosterone. 4. An email with the LD #1 on January 17, 2025, at 9:15 AM revealed 159 PSA patient tests and 10 testosterone tests were performed on the Beckman Coulter Access 2 Immunoassay System from December 11, 2024, to January 13, 2025. 5. An interview with the LD #1 on January 13, 2025 at 12:53 AM, confirmed laboratory staff failed to ensure quality control material for PSA and testosterone assays were not used past their expiration date per the manufacturer's instructions from December 11, 2024, to January 13, 2025.