Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D2065370	09/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Fore River Urology	21 Donald B Bean Drive, Suite 1, South Portland, ME	

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
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 record review and interview with testing personnel #2 (TP#2), the laboratory failed to follow manufacturer's instructions for reagent and control storage in the specialty of Chemistry. Findings include: 1. Record review on 9/25/2025 of manufacturer's pack incerts revealed the following: a. Serocare Urinalysis Calibrator kit: Store at 2-8C b. Serocare Total Bilirubin Reagent Kit: Store at 2-8C c. Serocare Specific Gravity Reagent Kit: Store at 2-8C d. Serocare pH reagent Kit: Store at 2-8C e. Serocare Nitrite Reagent Kit: Store at 2-8C f. Serocare Microprotein Reagent Kit: Store at 2-8C g. Serocare Microalbumin Reagent Kit: Store at 2-8C h. Serocare Hemoglobin Reagent Kit: Store at 2-8C i. Serocare Glucose Reagent Kit: Store at 2-8C j. Serocare Creatinine Reagent Kit: Store at 2-8C k. Serocare B-hydroxybutyrate Reagent Kit: Store at 2-8C l. MedTest Dx Pointe B-hydroxybutyrate Control Set: Store at 2-8C 2. Record review of the laboratory's refrigerator temperature monitoring log on 9/25/2025 revealed temperature range limits of 2C - 10C. 3. Staff interview with the TP#2 on 9/25/2025 at 11:30 AM, confirmed the acceptable range on the

	laboratory temperature chart was outside of the manufacturer's required storage parameters for the above referenced reagents and controls. 4. The laboratory performs 6,000 tests annually in the specialty of Chemistry.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on staff interview and record review the laboratory failed to adhere to the laboratory's corrective action policy when a refrigerator was not within temperature limits. Findings include: 1. Record review of the laboratory's refrigerator temperature log on 9/25/2025 revealed the refrigerator to be outside of noted temperature limits on 19 days between February and September 2025. 2. Record review of the Laboratory's Quality Assurance and Procedures revealed: "Corrective Actions: We have policies and procedures to follow when laboratory systems do not meet our performance specifications, such as when quality control or calibration is unacceptable, or improper storage temperatures occur". 3. Interview with TP#2 on 9/25/2025 at 11:30 AM revealed that the Laboratory Director had not been informed that the refrigerator was outside of temperature limits, no corrective action had been performed, and they were unaware of another policy instructing TP#2 what actions to take in this situation. 4. The laboratory performs 6,000 tests annually in the specialty of Chemistry.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on interview with Testing Personnel #2 (TP#2) and record review, the Laboratory Director (LD) failed to specify in writing the LD, Technical Supervisor (TS), and Technical Consultant in the list of duties policy. Findings include: 1. Record review of the laboratory's "Laboratory General Polices and Procedures" on 9/25/2025 revealed a name listed as LD and TS that is not a staff member of the laboratory. No TC was designated or duties listed. The policy was signed by the current LD on 9/6 /2025. 2. Interview with a staff nurse on 9/25/2025 at 10:00 AM confirmed the findings above. 3. The laboratory performs 6,000 tests annually in the specialty of Chemistry.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) failed to evaluate the competency of all testing personnel (TP) for the 6 required criteria in the specialty of Chemistry. Findings include: 1. Record review of the laboratory's 2025 TP competency records on 9/25/2025 revealed 2 of 2 moderate complexity TP did not have complete competency records. Specifically: a. TP#1, did not have documented "assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples"; and "direct observation of performance of instrument maintenance and function checks" by the TC.. b. TP#2, did not have documented "direct observation of performance of instrument maintenance and function checks" by the TC. 2. Record review on 9/25 /2025 of the laboratory's "Laboratory General Policies and Procedures" revealed "Use established competency checklists per each test system in the laboratory. The trainer must directly observe the staff member perform each task with a mix of performing calibrations, quality control, and blind sample testing as applicable...". 3. Record review on 9/25/2025 of the laboratory's Competency documentation revealed 5 competency assessment criteria: "I. Direct observation of routine task performance. II. Review of records (worksheets, AC & Maintenance records, outside proficiency specimens, etc.). III. Re-testing of previously analyzed specimens (external proficiency samples, patient samples). IV. Assessment of problem solving skills (questioning technician, written examination, mapping diagram, peer review). V. SOP review." 4. Staff interview with the TP#2 on 9/25/25 at 11:00 AM confirmed the above findings. 5. The laboratory performs 6,000 tests annually in the specialty of Chemistry.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform direct observation of performance of instrument maintenance and function checks for 2 of 2 testing personnel. Refer to D6046