

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2065370	(X3) Date Survey Completed 05/08/2024
Name of Provider or Supplier Fore River Urology	Street Address, City, State 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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD) the laboratory director failed to sign the validation documentation for Sciteck Diagnostics automated urinalysis analyzer chemistry testing. Findings include: 1. Record review on 5/8/2024 of the laboratory's Sciteck Diagnostics automated urinalysis analyzer validation documentation revealed the validation was not signed as reviewed and accepted by the laboratory director. 2. Record review of the laboratory's "Validation Studies" policy revealed, "Completed validation studies are reviewed by the Medical Director". 3. Staff interview with the LD on 5/8/2024 at 9:00 AM confirmed the LD did not sign the Sciteck Diagnostics automated urinalysis analyzer validation documentation. 4. The laboratory performs 6000 tests annually in the specialty of chemistry.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with laboratory director (LD), the laboratory director (LD) failed to ensure that an approved procedure manual was available to testing personnel. Findings include: 1. Record review of the laboratory chemistry testing manual on 5/8/2024 revealed no signature of approval by the LD. 2. Interview with the LD on 5/8/2024 at 9:00am confirmed the above findings. 3. The laboratory performs 6000 tests annually under the specialty of chemistry.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate the competency of testing personnel (TP) to perform moderate complexity testing in the specialty of chemistry. Findings include: 1. Record review on 5/8/2024 of the laboratory's 2023-2024 TP competency records revealed 1 of 1 new TP did not have competency records signed by the technical consultant (TC) or laboratory director (LD). 2. Record review on 5/8/2024 of the laboratory's "Personnel Orientation and Training" policy revealed: "Final approval of the ability of the employee to perform the specific task is by the Director or assign or designee." 3. Staff interview with the LD on 5/8/2024 at 9:30 am confirmed the above findings. 4. The laboratory performs 6000 tests annually in the specialty of chemistry.