

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0090304	(X3) Date Survey Completed 09/01/2022
Name of Provider or Supplier Waterville Family Practice	Street Address, City, State 31 Front Street, Waterville, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to include the reportable ranges for test results in the laboratory manual. Findings include: 1. Record review on 9/1/2022 of the laboratory's procedure manual revealed no reference ranges for the specialties of Chemistry and Hematology. 2. Interview with the laboratory manager on 9/1/2022 at 10:00am revealed the reference ranges had been omitted from the manual. 3. The laboratory performs 40,000 tests annually in the specialties of Chemistry and Hematology.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer on the Horiba Pentra C400 Chemistry analyzer. Findings include: 1. Record review on 9/1/2022 of the laboratory's manuals revealed no documentation of validation for the Horiba Pentra C400. 2. Interview with the laboratory manager on 9/1/2022 at 10:30am revealed that the analyzer was validated in 2015 but the documentation had been misplaced. 3. The laboratory performs 35,000 tests annually in the specialty of Chemistry.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(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 manager, 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 testing manual on 9/1/2022 revealed no signature of approval by the LD. 2. Record review of the "Qualifications and Responsibilities" chapter of the laboratory manual on 9/1/2022 revealed the statement: "The laboratory director is responsible for the overall operation and administration of the laboratory..." 3. Interview with the laboratory manager on 9/1/2022 at 9:00am confirmed the above findings. 4. The laboratory performs 40,000 tests annually in the specialties of Chemistry and Hematology.

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 Technical Consultant (TC) failed to evaluate the competency of all testing personnel (TP) to perform moderate complexity testing in the specialties of Chemistry and Hematology. Findings include: 1. Record review on 9/1/2022 of the laboratory's 2020 and 2021 TP competency records revealed, 6 of 6 moderate complexity TP did not have competency records performed by the TC. 2. Record review on 9/1/2022 of the laboratory's "Qualifications and Responsibilities" policy revealed the procedure revealed the statement, "The technical consultant... is responsible for maintaining and documenting... is responsible for observing and evaluating personnel". 3. Staff interview with the practice manager on 9/1/2022 at 10:00 PM confirmed the above findings. 4. The laboratory performs 40,000 tests annually in the specialties of Chemistry and Hematology.