Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2314642	07/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Patriot Laboratory Llc	2380 Sunset Point Rd, Clearwater, FL	

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
D0000	An announced CLIA initial survey was conducted at Patriot Laboratory LLC on 7/07 /25. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 review of the laboratory manual and interview, the procedure manual failed to include a procedure for performing manual whole blood smears, and imminently life-threatening test results, or panic or alert values from 3/31/25 to 7/7/25. Findings

	included: 1. The laboratory manual was approved by the Laboratory Director 3/29 /2025. The approved laboratory manual failed to include written approved procedure for manual whole blood smears, and imminently life-threatening test results, or panic or alert values. 2. The Technical Consultant on 7/7/2025 at 4:15 p.m. confirmed the procedure manual failed to include a procedure for performing manual whole blood smears, and imminently life-threatening test results, or panic or alert values.
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, record review, and interview, the laboratory failed to define criteria for proper storage of Multichem S Plus Quality Control reagent consistent with the manufacturer's instructions for freezer temperature from 1/29/25-7/7/25. Findings included: 1. The Multichem S Plus Quality Control reagent was observed stored in the freezer on 7/7/2025 at 10:55 a.m. The acceptable temperature limits for the Multichem S Plus Quality Control reagent was listed on the packaging as -20 to -80 degrees Celsius. 2. The Daily Thermometer Temperature Reading Log for the freezer documented the acceptable range defined by the laboratory was -15 to -25 degrees Celsius. 3. The Technical Consultant confirmed 7/7/2025 at 4:15 p.m. the laboratory's defined acceptable range for the freezer was not consistent with the manufacturer's instructions for freezer temperature for storage of the Multichem S Plus Quality Control reagent.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain records of patient urine microscopic testing from 3/31/25 to 7/7/2025. Findings included: 1. Patient #1 test report from 7/02/25 documented a urine dipstick and urine microscopic test was performed and reported. 2. The laboratory had a record of results for the urine dipstick, however there was no record of the urine microscopic test which was performed and reported. 3. The Technical Consultant confirmed on 7/7/2025 at 4:15 p. m., the laboratory had not been retaining a record of any of the patient urine microscopic test performed and reported by the laboratory.
D5801	TEST REPORT CFR(s): 493.1291(a)

	(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and interview, it was determined the laboratory failed to verify the Laboratory Information System (LIS) to ensure test results and other patient-specific data were accurately and reliably sent from the point of data entry to final report destination including results reported from calculated data for Chemistry, Urinalysis, Endocrinology, Toxicology, and Hematology testing performed by the laboratory. Findings included: 1. Review of verification records for Chemistry, Urinalysis, Endocrinology, Toxicology, and Hematology testing performed by the laboratory showed the laboratory failed to include verification of the LIS system including calculated data. 2. The Technical Consultant on 7/7/25 at 4:15 p.m. confirmed the laboratory had not verified the LIS for Chemistry, Urinalysis, Endocrinology, Toxicology, and Hematology testing performed by the laboratory including calculated data.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based record review and interview, the Laboratory Director failed to ensure that the quality control (QC) program for the Beckman DXH500 Hematology Analyzer was established and maintained to assure the quality of laboratory services provided from one of one new lot change. Findings included: 1. The laboratory manual approved by the Laboratory Director 3/29/2025, included a procedure for new lots of controls. The New Lot of Controls process was to perform lot to lot on all new lots with 5 separate points for assayed control, if the means were not within the assay range contact Technical Services and document in the appropriate lot to lot form. The Beckman DXH500 Hematology Analyzer QC used assayed controls. 2. The laboratory had a lot change of the QC for the Beckman DXH500 Hematology Analyzer on 7/03/2025. It was documented in the laboratory QC records and on the package insert Lot 3525174 replaced Lot 3525172 on 7/03/2025. There was no documentation available for review of the laboratory following the written procedure for new lots of controls or that the Laboratory Director ensured the procedure was followed. 3. The Technical Consultant confirmed on 7/7/25 at 4:15 p.m. the laboratory had not followed the written procedure for new lots of controls when Lot 3525174 was put into use on the Beckman DXH500 Hematology Analyzer.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patient specimens, all personnel had demonstrated that they could perform all testing operations reliably to provide and report accurate results for two of two Testing Personnel (TP#A and TP#B). Findings include: 1. The CMS-209 Laboratory Personnel Report signed by the Laboratory Director on 4/23/25 listed two testing personnel TP#A and TP#B. 2. The laboratory manual approved by the Laboratory Director on 3/29/2025, included in the Quality Assurance Plan, a section on Personnel which stated competency was to be completed for testing personnel upon hire. 3. TP#A's and TP#B's personnel records failed to include competency of performing all testing prior to performing patient testing as required. There was no evidence the Laboratory Director had ensured the procedure for personnel had been followed. 4. The Technical Consultant (who is also TP#A) confirmed there was no record of demonstrating competency of performing all testing prior to performing patient testing as required.