

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1091069	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Patient First - Taylor Road	Street Address, City, State 2425 Taylor Road, Chesapeake, VA	
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 recertification survey was conducted at Patient First-Taylor Road on April 24, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of daily temperature/environment logs, lack of documentation, procedures, and interviews, the laboratory failed to retain documentation of monitoring daily relative humidity percent (%) and room/refrigerator/freezer temperatures per their protocols for eight (8) of twenty-three (23) months as reviewed on the date of the inspection on August 24, 2025 (survey timeframe 5/2/23-4/24/25). Findings include: 1. Review of the laboratory's environmental log records for the 23 month survey timeframe (5/2/23 - 4/24/25) revealed no documentation of laboratory room temperature/humidity or refrigerator/freezer temperature monitoring for the following 8 months in calendar year 2023: May, June, July, August, September, October, November, December. The inspector requested to review documentation of temperature monitoring for the 8 months outlined above. The records were not available for review. 2. Review of the laboratory's procedures revealed Quality</p>

Assurance protocol (Section 14, Equipment-Temperature/Humidity Checks) that outlined daily monitoring of environmental conditions. The policy stated, "The temperature of the laboratory refrigerator and freezer and the temperature of of the room will be read and recorded on the Temperature Humidity Chart". 3. An interview with the Technical Consultant and laboratory supervisor on 4/24/25 at 1:30 PM confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a tour, review of hematology analyzer maintenance logs, lack of documentation, procedures, and interviews, the laboratory failed to document required hematology analyzer maintenance protocols for eight (8) of twenty-three (23) months reviewed on the date of the inspection on April 24, 2025 (timeframe of review 5/2/23-4/24/25). Findings include: 1. During a tour of the laboratory the inspector noted that the Pentra 60+ hematology analyzer's maintenance logs required the following schedule of required procedures: Daily - check reagents, perform start up, general cleaning, shutdown; Weekly - perform concentrated cleaning, back flush, rinse cytometer; Bi-Weekly - empty cap piercing filter-monthly based on volume. 2. A review of the laboratory's Pentra 60+ hematology maintenance logs for the review timeframe of 5/2/23 -4/24/25 revealed no maintenance documentation for the following months in calendar year 2023: May, June, July, August, September, October, November, December. The inspector requested to review the maintenance logs. No records were provided. 3. The inspector inquired regarding the above 8 months' lack of documentation. The laboratory supervisor stated on 4/24/25 at noon, "The analyzer maintenance is required by the manufacturer to be documented as outlined on our log sheets. During the preparation for this inspection, I realized that some of the records were missing". 4. An interview with the Technical Consultant and laboratory supervisor on 4/24/25 at 1:30 PM confirmed the above findings.

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:
A. Based on a review of procedures, quality control (QC) and test logs, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that documentation of serum human chorionic gonadotropin (hCG) quality measures were monitored/retained (controls, reagent lot number and expiration dates) per established protocols for eight (8) of twenty-three (23) months while one hundred seven (107) patient tests were reported as noted on the date of the inspection on August 24, 2025 (survey timeframe 5/2/23-4/24/25). Findings include: 1. Review of the laboratory procedure manuals revealed an Individualized Quality Control Plan (IQCP) protocol for monitoring Beckman Coulter ICON 20 hCG serum pregnancy tests' analytic

quality that outlined: IQCP ICON 20 Serum hCG - Analytic Measure - "Record lot numbers, expiration dates of reagents, and QC, check expiration dates." IQCP ICON 20 Serum hCG - Test System Internal Procedural Controls - "Document the acceptability of the internal control with each patient result on the hCG test log." 2. Review of the laboratory's ICON hCG Serum log records for the 23 month survey timeframe (5/2/23 - 4/24/25) revealed no documentation for the following 8 months in calendar year 2023: May, June, July, August, September, October, November, December. 3. The inspector requested to review the ICON test logs for QC, lot number and expiration dates for the 8 months outlined above. The records were not available for review. 4. Review of 2023 test logs revealed the following number of patient serum hCG results were reported for the timeframe outlined above: May 8 June 16 July 12 August 9 September 15 October 15 November 16 December 16 A total of 107 serum hCG test results were reported. 5. An interview with the Technical Consultant (TC) and laboratory supervisor on 4/24/25 at 1:30 PM confirmed the above findings. B. Based on a review of procedures, hematology Wright Stain QC and test logs, lack of documentation, and interviews, the LD failed to ensure documentation of stain quality was monitored/retained per established quality assurance (QA) protocol for 8 of 23 months while reporting eighty-four (84) manual differential results noted on the date of the inspection on August 24, 2025 (survey timeframe 5/2/23-4/24/25). Findings include: 1. Review of the laboratory procedure manuals revealed a Wright Stain QA protocol that outlined, "After observing staining characteristics of control slide, complete Wright Stain Quality Control Log each day of testing each month." 2. Review of the laboratory's Wright Stain log records for the 23 month survey timeframe (5/2/23 - 4/24/25) revealed no documentation for stain quality during the following 8 months in calendar year 2023: May, June, July, August, September, October, November, December. 3. The inspector requested to review the Wright Stain Quality logs for the 8 months outlined above. The records were not available for review. 4. Review of 2023 patient test logs revealed the following number of manual differential slides were tested and reported: May 7 June 8 July 5 August 10 September 9 October 15 November 13 December 17 A total of 84 Wright stained manual differential slides were assayed. 5. An interview with the TC and laboratory supervisor on 4/24/25 at 1:30 PM confirmed the above findings.