Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306172	05/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
John Paul Jones Hospital	317 Mcwilliams Avenue, Camden, AL	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC), the laboratory failed to implement a mechanism to verify the accuracy of the Ammonia (NH3+), urine Total Protein (uTP) and C-Reactive Protein (C-RP), all non-regulated analytes. The surveyor noted the PT evaluation failures occurred in two of the seven Specialties /Subspecialties from 2023-2025. The findings include: 1. A review of the API PT records revealed the laboratory had unsuccessful evaluations for the Chemistry and Immunology specialties for the following events: A) 2023 Chemistry 2nd Event; NH3+ 67% and uTP 33% B) 2024 Chemistry 1st Event; NH3+ 33% and uTP 33% C) 2023 Immunology 1st Event; C-RP 50% D) 2023 Immunology 2nd Event, C-RP 0% 2. A further review revealed no evidence of accuracy verification for the failing analytes. 3. An interview with the TC on 05-20-2025 at approximately 1:43 PM revealed the PT unsuccessful evaluations for these events resulted when the reported values were not converted to the correct units and improper mixing techniques. The same reasons were documented under the Laboratory Director's (or designee) review of PT evaluations.
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 reviews of the 2023-2025 Freezer Temperature (FT) logs, the Policy and Procedure Manual (P&P), the Laboratory Information System (LIS) patient testing history data and an interview with Technical Consultant (TC), it was determined the laboratory failed to monitor and document the FT for 6 of the 30 days in November 2023. The findings include: 1) A review of the FT logs revealed the laboratory failed to monitor and document the FT where reagents/materials for patient testing were stored for the following days: A) November 2023; 4, 11-12, 18-19, 25. 2) A review of the P&P revealed the test cartridges for the D-Dimer and Troponin testing were in this freezer and had to be maintained at minus 20 degrees Celsius or colder for storage requirement. 3) The LIS patient testing history data revealed there was one patient D-Dimer test completed on 11-12-2023. 4) The TC confirmed the above findings on 05-21-2025 at 3:25 PM during the day 2 exit conference.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on reviews of the Blood Bank (BB) patient records, BB Reagent logs and an interview with the Technical Consultant (TC), the surveyor determined the laboratory had utilized reagents/materials after expiration date for patient testing. The surveyor noted the expired materials were used for 1 of the 30 days in April 2025. The findings include: 1. A review of the BB patient records revealed the following reagent /materials with Lot number CNF383, Expiration Date of 04-29-2025 were used for one patient testing on 04-30-2025. A) Confidence Cell 1 B) Confidence Cell 2 C) Confidence Antibody 2. A review of the BB Reagent logs revealed the laboratory had not added these reagent/materials on the log. 3. TC confirmed the above findings during Day 2 exit conference with the TC and hospital CEO on 05-21-2025 at 3:25 PM.
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 review of the Beckman Coulter (BC) DxH 560 maintenance records, and an interview with the Technical Consultant (TC), the laboratory failed to document the monthly and 8-month maintenance. This was noted for 5 of the 23 months

	reviewed from 2023-2025. The findings include: 1. A review of the BC DxH 560 maintenance records revealed no evidence of monthly and 8 month maintenance documentation for the following months: A) April and October 2023 B) January and August 2024 C) February 2025 2. A further review of the BC DxH 560 Maintenance Log revealed the following maintenance specifications. A) Monthly (Clean WBC Bath Filter) B) 8-Months (Lubricate Pistons and Replace Rinsing Head O-Ring) 3. During the day 2 exit conference with the TC and hospital CEO on 05-21-2025 at 3: 25 PM, the TC confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on reviews of the Chemistry Quality Control (QC) logs, Patient records, Policy and Procedure Manual (P&P) and an interview with the Technical Consultant, the laboratory failed to ensure two levels of QC were performed and documented each day of patient testing. The surveyor noted one of the two Bio-Rad Multiqual (BRM) QC levels was not performed for 1 of 31 days reviewed for January 2024. The findings include: 1. A review of the Chemistry QC logs revealed the laboratory failed to perform the BRM QC level 3 prior to patient testing on 01-21-2024. There were five patients tested and results reported that day. 2. A review of the laboratory's P&P manual revealed the laboratory's requirement to run two levels of QC each day of patient testing. 3. The TC confirmed the above findings on 05-21-2025 at 3:25 PM during the day 2 exit conference with the hospital CEO.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview the Technical Consultant (TC), the TC failed to assess competency at least semi-annually in the first year of patient testing. This was noted for 2 of the 14 Testing Personnel (TP) listed on the CMS 209 (Laboratory Personnel Report) from 2023-2025. The findings include: 1. A review of personnel records revealed TP4 and TP14 had the semi-annual competency assessment performed and signed by TP3. There was no documentation the TC assessed TP4 and TP14 during the first year of patient testing. 2. The TC confirmed the above findings on 05-21-2025 at 3:25 PM during the day 2 exit conference with the hospital CEO.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually

	This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview the Technical Consultant (TC), the TC failed to assess competency annually after the first year of patient testing. This was noted for 2 of the 14 Testing Personnel (TP) listed on the CMS 209 (Laboratory Personnel Report) from 2023-2025. The findings include: 1. A review of personnel records revealed TP4 and TP14 had the annual competency assessment performed and signed by TP3. There was no documentation the TC assessed TP4 and TP14 when the annual competency evaluation was due. 2. The TC confirmed the above findings on 05-21-2025 at 3:25 PM during the day 2 exit conference with the hospital CEO.