Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306172	10/10/2018
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interviews with the Technical Consultant [Testing Personnel #1 (TP #1)], the surveyor determined the laboratory failed to establish a written policy and procedure for quality control testing for the Hemochron Jr, a Coagulation analyzer, installed in December of 2016 and used for a back-up instrument to the Hemochron Elite. The findings include: 1. During the initial tour of the laboratory on 10/10/18 at 9:45 AM, TP #1 stated in December of 2016 a back-up Coagulation (Prothrombin/INR) analyzer was installed. TP #1 stated the analyzer was run at least once per month. TP #1 also stated the

	laboratory had not developed an IQCP (Individualized Quality Control Plan) for the Hemochron Jr, and two levels of quality control were tested each day of patient testing on the Hemochron Jr. 2. In an interview on 10/10/18 at 4:10 PM, the surveyor asked TP #1 to clarify the quality control testing for Coagulation, because two manuals were provided with different quality control results documented differently. TP #1 confirmed no IQCP had been established for the Hemochron Jr, which was run rarely, but two levels of controls were tested each day the instrument was used. TP #1 also stated the Hemochron Jr did not have an internal quality control check like the Hemochron Elite analyzer. TP #1 stated there was no documented written quality control policy and procedure for the Hemochron Jr.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 a review of personnel educational and training records [Arterial Blood Gas (ABG) Manual] and an interview with the nurse supervisor of the ABG department, the laboratory director failed to ensure the testing personnel presented with the appropriate educational credentials, prior to testing patients' specimens. The laboratory director also failed to ensure the testing personnel received the appropriate training comparable to this moderate complexity testing (ABGs). This affected six of thirteen laboratory testing personnel. The findings include: 1. The manual for Arterial Blood Gas testing and personnel records, provided by the laboratory on 10/10/18, did not include educational credentials for the testing personnel in the ABG department, who had not previously qualified on the CMS form #209 (Personnel Form). 2. In an interview on 10/10/18 at 3:42 PM, the nurse supervisor of the ABG department clarified who the testing personnel of the ABGs were. These testing personnel (TP) were TP #4, 5, 6, 7, 8, 9, 10, 11, 12 and 13. Of these ten personnel, six of them had not previously qualified as testing personnel. When asked to present the educational credentials of the testing personnel, the nurse supervisor presented educational credentials for TP #8, #10, and #13. Appropriate educational credentials were not provided for TP #9, #11 or #12. The nurse manager stated she thought only the personnel who performed an arterial stick (blood collection) was included on the CMS form #209, and not actually the testing personnel. The nurse supervisor confirmed TP #8, #9, #10, #11, #12 and #13 were testing patient specimens. The nurse supervisor also confirmed she could not provide the appropriate educational credentials for TP #9, #11 and #12. 3. Further review of the personnel records in the manual revealed "RESPIRATORY THERAPY CHECKLIST FOR RE-EVALUATION" for each of the testing personnel. Noted on each of the checklists for TP #8 - #13 were handwritten notes which indicated: Able to process specimens but not authorized to obtain ABGs. 4. These checklists included blanks for dates for semi-annual and annual... 1) Knowledge of procedure and purpose of test 2) Preparation of equipment 3) Quality Control Procedure 4) Explanation to the patient 5) Preparation of site 6) Technique and skill in obtaining sample 7) Handling of sample 8) Care of site after sample drawn 9) Knowledge and use of machine 10) Documentation of results 11) Appropriate follow-up with MD after results are obtained 12) Knowledge of normal

	and panic values 5. In an interview on 10/10/18 at 3:42 - 4:08 PM, the surveyor asked the nurse supervisor of the ABG department to explain the initial training and semi-annual/annual reviews for any testing personnel who was employed for one year or greater, and what the dates on the checklists indicated. The nurse supervisor explained the note indicating processing meant the personnel actually tested patient specimens. The nurse supervisor stated testing personnel #8 - 13 had been educated on how to run an ABG specimen by her showing them which buttons to push on the instrument; but no specimens had been utilized. The nurse supervisor stated she thought CLIA was concerned with personnel, who performed arterial sticks and not actually performed the testing; hence, training and evaluations were not performed and documented, according to the CLIA regulations. Additionally, the nurse supervisor stated the department only had about six patient specimens for the year, and thus no patient specimens could be used for training (usually not enough volume to save). Also, the nurse supervisor confirmed no quality control or calibration material had been used to train the personnel. The nurse supervisor also stated the physician (listed on the #209 as the Technical Consultant of the ABG department, but was not found qualified during the on-site survey) who signed the checklists was indicating with his signature the employee could run the instrument. The Laboratory Director had delegated technical supervision to this physician (who was not proven qualified to be a technical consultant). At the time of the survey, the dates of hire were not yet determined. 6. On October 15, 2018, the CLIA State Agency received a fax from the laboratory with dates of hire for the nurses who worked in the ABG Department. Indicated on this fax was the following dates of hire: TP #9 was hired on 1/16/2018 with a date of "2 -18" only specified on the checklist for re-evaluation. A semi-annual competency evaluation was not documented for TP #9. TP #11 was hired on 6/1/2012; but failed to present the appropriate educational credentials. The checklist for TP #11 specified dates occurring each year in June, from 2012 - 2018. For TP #11, the surveyor was not able to determine a semi-annual competency was ever performed. TP #12 was hired on 8/14/2014; but failed to present the appropriate educational credentials. 7. Any laboratory testing personnel performing CLIA certified testing of moderate complexity should receive initial laboratory training, a semi-annual competency assessment, during the first year of employment, and an annual competency assessment each year.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of personnel records, a lack of documentation, a review of the policy and procedure manuals, and interviews with Testing Personnel #1 (also one of two technical consultants, initially listed on the CMS 209 Personnel Form) and the Supervisor of the ABG (Arterial Blood Gases) Department, the surveyor determined the Laboratory Director delegated technical aspects of the ABG department to a physician, who had not provided the documentation of qualifications to be a technical

	consultant (of moderate complexity testing). The findings include: 1. A review of the CMS Personnel Form revealed the laboratory had listed a physician as one of two technical consultants. 2. At 11:00 AM on 10/10/18, the surveyor asked to see the educational credentials, laboratory experience and training of the personnel (physician) listed on the CMS Personnel Form as the technical consultant. At this time, the surveyor discussed with Testing Personnel #1 (TP #1) the requirements for the technical consultant. The laboratory experience and training was not provided; thus TP #1 crossed the physician off the personnel form as technical consultant. 3. A review of the Respiratory Policy and Procedure Manual, Volume One, revealed the physician mentioned above had signed as the reviewer, along with the hospital administrator and the supervisor of the ABG Department. The policy and procedure manual was not signed by the director. The physician was indicated in the manual as Respiratory Therapy Medical Advisor and Technical Director. The respiratory manuals included a letter of delegation from the Laboratory Director, outlining the technical supervisory/consultation of the ABG Department to the above mentioned physician. 4. The Respiratory Policy and Procedure Manual included checklists, entitled RESPIRATORY THERAPY CHECKLIST FOR RE-EVALUATION, for the personnel in the ABG Department, which were signed by the above mentioned physician. 5. In an interview on 10/10/18 at 3:42 - 4:08 PM, the Supervisor of the ABG Department (Respiratory Unit) stated the physician was named to replace the former physician. The surveyor provided the qualification requirements for Technical Consultant and discussed with the supervisor the delegation of certain responsibilities from the Laboratory Director to a qualified Technical Consultant (of moderate complexity testing). 6. The surveyor discussed letters of delegations to qualified personnel with TP #1, at 4:10 PM on 10/10/18. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor