Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0306172	09/09/2021
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the GEM Premier 3500 SOP (Standard Operating Procedures), and an interview with Testing Personnel #3 (the Respiratory Therapy [RT] Supervisor), the laboratory failed to ensure the Laboratory Director reviewed /approved the procedures before the testing personnel utilized the new instrument for patient testing on 4/28/2021. The findings include: 1. A review of the GEM Premier 3500 SOP reviewed no documentation of review/approval (as indicated by a signature and date) of the procedures by the Laboratory Director. The testing personnel began using the instrument for patient tests on 4/28/2021. 2. In an interview on 9/9/2021 at 10:12 AM, Testing Personnel #3 (the RT Supervisor) stated the IL (Instrumentation Laboratory) Technician had emailed the procedures, however she did not realized the significance of the document, and failed to forward the SOP to the Laboratory Director for his review/approval and signature/date. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration verification (C/V) records for the GEM 3000 Blood Gas analyzer, and an interview with Testing Personnel #3 (the Respiratory Therapy Supervisor), the laboratory failed to perform C/V's every six months in 2020 and early 2021, as required by CLIA regulations. The findings include: 1. A review of the records for the GEM 3000 revealed the each new reagent cartridge on the instrument was calibrated using GEM CVP (Calibration Valuation Product) 1 and 2. As per CLIA regulations, tests calibrated with less than three calibrators require semi-annual C/V. 2. A review of 2018-2021 GEM 3000 Blood Gas analyzer records revealed C/V's were performed on 2/5/2019 and 8/6/2019, however there was no documentation of C/V's performed in 2020 or early 2021. (A new instrument was installed April 2021.) 3. In an interview on 9/9/2021 at 11:55 AM, Testing Personnel #3 confirmed C/V's should be performed every six months, and no C/V's were performed on the GEM 3000 in 2020-2021. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Triage Meter installation documents, D-Dimer quality control (QC) records and an interview with the Laboratory Manager, the surveyor determined the laboratory failed to perform QC every day of patient testing in the absence of an IQCP (Individualized Quality Control Plan). This occurred eight months (February thru September) in 2021. The findings include: 1. During the entrance tour on 9/8 /2021 at approximately 10:30-11:00 AM, the Laboratory Manager listed the Triage Meter as a new instrument; D-Dimer (a moderate-complexity Hematology test) was performed on the Triage Meter. The surveyor asked how often the laboratory performed D-Dimer QC; the Manager stated QC was performed every thirty days and with each new lot numbers of cartridges, as per manufacturer's instructions. When asked if the laboratory had implemented an IQCP to allow for decreased frequency of QC testing, the Manager stated the Triage technician had not told her about this requirement. 2. A review of the validation study for the Triage D-Dimer revealed the

	Laboratory Director approved the test on 2/1/2021; at approximately 3:20 PM on 9/8 /2021 the Laboratory Manager confirmed patient testing began on the same date (2/1 /2021). 3. A review of the Triage D-Dimer records revealed the laboratory performed QC on 1/29, 3/2, 4/13, 5/23, 5/26, 6/24, 7/26, and 8/23/2021. During the exit summation on 9/9/2021 from 2:25 to 2:45 PM, the Laboratory Manager confirmed patient D-Dimers were run on other days when QC was not performed, and the laboratory had not implemented an IQCP. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for 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 reviews of personnel files and interviews with Testing Personnel #3 (the Respiratory Therapy [RT] Supervisor) and the Laboratory Manager / Technical Consultant, the Technical Consultant failed to perform and document the semi-annual competency evaluation due mid-2019 for one of one new Testing Personnel (TP) who had performed patient Arterial Blood Gas (ABG) testing. [Not performing and documenting competency assessments on Testing Personnel performing ABG's is a repeat deficiency.] The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed one new moderate-complexity TP who only performed ABG testing; TP #8 was hired and trained in February 2019. 2. A review of the personnel file for TP #8 revealed the GEM Premier 3500 training, dated 4/29 /2021, and the 2/14/2019 training on the Gem 3000 ABG analyzer in use when he was hired. There was no documentation of a semi-annual competency assessment due around August 2019. 3. During an interview on 9/8/2021 at 4:20 PM, the surveyor requested the competency evaluations for the testing personnel who performed ABG's. TP #3 (the RT Supervisor) stated they only did "competencies" when they trained the staff. 4. During the Day 2 entrance interview on 9/9/2021 at 9:40 AM the surveyor discussed concerns related to competency assessments for the RT testing personnel. The surveyor asked the Laboratory Manager / Technical Consultant (TC) if she was aware that in the Plan of Correction (with the effective date of 11/1/2018) for deficiencies from the previous survey, the Laboratory Director had delegated "the performance review evaluations of respiratory personnel" to the TC. The TC answered, "Yes, I am", and confirmed she had failed to ensure the evaluations were performed. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on reviews of personnel files and interviews with Testing Personnel #3 (the Respiratory Therapy [RT] Supervisor) and the Laboratory Manager / Technical Consultant, the Technical Consultant failed to perform and document annual

	competency evaluations due in 2018 thru 2021 for six of six Testing Personnel (TP) who had performed patient Arterial Blood Gas (ABG) testing. [Not performing and documenting competency assessments on Testing Personnel performing ABG's is a repeat deficiency.] The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed six moderate-complexity TP who only performed ABG testing. TP #3 thru #7 were employed since the previous survey (10 /10/2018), and TP #8 was hired and trained in February 2019. 2. A review of personnel files revealed training only on the new GEM Premier 3500 ABG analyzer for TP #3 thru #7. TP #8's file included GEM Premier 3500 training, and the 2/14 /2019 training on the Gem 3000 ABG analyzer in use when he was hired. There was no documentation of competency assessments for any of the TP for the 2018-2021 period. 3. During an interview on 9/8/2021 at 4:20 PM, the surveyor requested the competency evaluations for the testing personnel who performed ABG's. TP #3 (the RT Supervisor) stated they only did "competencies" when they trained the staff. 4. During the Day 2 entrance interview on 9/9/2021 at 9:40 AM the surveyor discussed concerns related to competency assessments for the RT testing personnel. The surveyor asked the Laboratory Manager / Technical Consultant (TC) if she was aware that in the Plan of Correction (with the effective date of 11/1/2018) for deficiencies from the previous survey, the Laboratory Director had delegated "the performance review evaluations of respiratory personnel" to the TC. The TC answered, "Yes, I am", and confirmed she had failed to ensure the evaluations were performed. .
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the validation records for the GEM Premier 3500 Arterial Blood Gas (ABG) analyzer and the Triage Meter (for D-Dimer testing), and interviews with Testing Personnel #3 (the Respiratory Therapy [RT] Supervisor) and the Laboratory Manager / Technical Consultant, the surveyor determined the Laboratory Director failed to document review/approval of the validations before patient testing began. This affected two of three new instruments installed since the previous survey on 10 /10/2018. The findings include: 1. A review of the GEM Premier 3500 ABG analyzer revealed precision, accuracy and reportable range were validated by the IL (Instrumentation Laboratory) Technician on 4/28/2021. However, there was no documentation of the LD's review (as indicated by a signature and date) signifying his approval of the studies as verification of the manufacturer's performance specifications. 2. During an interview on 9/8/2021 at 3:30 PM, Testing Personnel #3 (the RT Supervisor) stated the IL Technician told her the validation was "OK", and she did not know the Laboratory Director had to review and approve the studies. The surveyor then asked when patient ABG testing began; the Supervisor stated, "4/28 /2021". 3. A review of the D-Dimer validation on the new Triage Meter revealed the Laboratory Manager / Technical Consultant (TC) ran reportable range studies and two levels of quality control (QC) once (insufficient to establish precision) on 1/29/2021. The TC also sent seven patient specimens to a reference laboratory and compared the results to the Triage D-Dimer results (to validate accuracy). However, the reference laboratory used a different test methodology and results were reported in different units of measurement. 4. During an interview on 9/8/2021 at approximately 3:10 PM,

	the TC was unable to explain how the above D-Dimer comparison study proved the accuracy of the Triage Meter. The TC confirmed the Laboratory Director had signed /approved the comparison study on 2/1/2021, however he had failed to review the validation studies performed on 1/29/2021. The surveyor also explained running the QC one time was not enough to establish precision; the QC records documented QC had been performed multiple times, however the laboratory had not analyzed the data to statistically calculate the precision of the instrument. The surveyor then asked when patient D-Dimer testing on the Triage Meter began; the TC answered, "2/1/2021". SURVEYOR ID #32258 Licensure and Certification Surveyor