Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2133946	08/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pelican Hill Medical Center	470 Pleasant Hill Road, Nw, Lilburn, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 8, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. An immediate jeopardy situation was identified due to the laboratory's inability to employ qualified testing personnel, failure to employ a qualified technical consultant, failure of the laboratory to monitor and evaluate the overall quality of the analytic systems and correct identified problems for each speciality performed, and failure of the laboratory director (LD) to provide overall laboratory management and direction. The following deficiencies were cited:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the testing personnel (TP) and laboratory director (LD) failed to attest to the routine integration of the samples into the patient workload as required. Findings include: 1. American Proficiency Institute (API) document review revealed the LD and TP failed to sign the attestation statements for the following Hematology PT events: 2017 -- third event; 2018 -- first and second events. 2. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6:00 p.m. confirmed the LD and TP did not sign the aforementioned PT attestation statements.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings include: 1. SOP review revealed the laboratory failed to establish and follow written policies and procedures, including the six required procedures, to assess employee competency in the speciality of hematology. 2. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6 p.m. confirmed the SOP did not contain a hematology competency policy .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as required. Findings include: 1. SOP review revealed the laboratory failed to establish and follow a quality assurance policy and procedure. 2. An interview with Staff #2 (CMS 209) on 8/8/2018 in an office area at approximately 6:00 p.m. confirmed the laboratory SOP did not contain a quality assurance policy and procedure.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of quality assessment, quality control, and calibration documentation, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems for each specialty of testing performed. Findings include: Refer to D5401, D5413, D5421, D5439, and D5441
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a written policy and procedure for all tests, assays, and examinations performed by the laboratory as required. Findings include: 1. SOP review revealed the following policies and procedures were not available at the time of survey: critical values, proficiency testing, venipuncture, calibration or calibration verification, and temperature and humidity. 2. An interview with Staff #2 (CMS 209) on 8/8/2018 in an office area at approximately 6:00 p.m. confirmed the laboratory SOP did not contain policies and procedures for the aforementioned tests, assays, and examinations at the time of survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 laboratory maintenance document review and staff interview, the laboratory failed to monitor the laboratory conditions required for patient testing. Findings include: 1. Laboratory maintenance document review revealed laboratory humidity was not monitored and documented for the Emerald Cell-Dyn for 2017 and 2018 thus far as specified by the manufacturer. 2. An interview with Staff #2 (CMS 209) on 8/8 /2018 in an office area at approximately 6:00 p.m. confirmed laboratory humidity was neither monitored nor documented for 2017 and 2018 thus far.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) documents and staff interview, the laboratory failed to establish and verify performance specifications for the

	hematology analyzer. Findings include: 1. Emerald-Cell Dyn hematology analyzer document review revealed the laboratory failed to establish and verify performance specifications for the following performance characteristics: accuracy, precision, and reportable range. 2. At the time of the survey there were was no comparison study available for 2017 and 2018 thus far. 3. At the time of the survey there were no linearity documents for 2017 and 2018 thus far. 4. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6:00 p.m. confirmed performance specifications had not been established and verified for the Emerald Cell-Dyn. During the same interview, Staff #2 (CMS 209) confirmed there was no comparison study performed in 2017 and 2018 thus far. During the same interview, Staff #2 (CMS 209) confirmed there were no linearity documents available for the Emerald Cell-Dyn for 2017 and 2018 thus far.
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 review of hematology instrument calibration documents and staff interview, the laboratory failed to perform calibration every six months as required. Findings include: 1. Emerald Cell-Dyn hematology analyzer calibration document review revealed instrument calibration was not performed between 9/6/17 and 8/8/2018. 2. An interview with Staff #2 (CMS 209) on 8/8/2018 in an office area at approximately 6:00 p.m. confirmed the Emerald Cell-Dyn was not calibrated between 9/6/17 and 8/8 /2018.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the

	laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of the hematology analyzer as required. Findings include: 1. Emerald Cell-Dyn QC document review revealed there were no Levey-Jennings charts for 2017 and 2018 thus far. 2. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6: 00 p.m. confirmed there were no Levey-Jennings charts for 2017 and 2018 thus far.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the following documents: policy and procedure manual (SOP), quality control (QC), testing personnel (TP) , quality assessment (QA), and proficiency test (PT), and staff interview, the laboratory director (LD) failed to provide overall laboratory management and direction. Findings include: Refer to D5401,D5413, D5421, D5439, D5441, D6018, D6019, D6032, D6033, D6035, D6053, This condition-level deficiency contributed to the Immediate Jeopardy
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interview, the laboratory director (LD) failed to review the PT performance evaluations as required. Findings include: 1. American Proficiency Institute (API) document review revealed the LD failed to review the PT performance evaluations as required for the following Hematology PT events: 2017 -- third event; 2018 -- first and second event. 2. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6: 00 p.m. confirmed the LD did not review the PT performance evaluations for the aforementioned events.

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) document review and staff interview, the laboratory director (LD) failed to ensure corrective action was performed for unsatisfactory PT results as required. Findings include: 1. American Proficiency Institute (API) document review revealed corrective action was not performed for 2017 Hematology Event #3 with an 80 percent test score. 2. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6:00 p.m. confirmed corrective action was not performed for the aforementioned PT event.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) , the laboratory director (LD) failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of preanalytic, analytic, and postanalytic phases of testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in all phases of laboratory testing. 2. An interview with Staff #2 (CMS 209) in an office area on 8/8/2018 at approximately 6 p.m. confirmed the LD did not specify in writing the duties and responsibilities of each person engaged in all phases of laboratory testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview, the laboratory failed to employ an individual qualified to perform the duties and responsibilities of Technical Consultant (TC). Findings include: Refer to D6035 This condition- level deficiency contributed to the Immediate Jeopardy.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and staff interview, the laboratory failed to employ an individual qualified to perform the duties and responsibilities of Technical Consultant (TC). 1. TP document review revealed the laboratory failed to employ as individual qualified to perform the duties and responsibilities of TC due to lack of documentation of education and experience. 2. An interview with Staff #2 (CMS 209) on 8/8/2018 in an office area at approximately 6:00 p.m. confirmed no employee was qualified to perform the duties and responsibilities of TC due to lack of education documentation and experience. This deficiency contributed to the Immediate Jeopardy.

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 document review and staff interview, the technical consultant (TC) failed to perform a semi-annual competency for testing personnel (TP) as required. Findings include: 1. Based on TP document review and staff interview the TC failed to perform a semi-annual competency in 2018 for the following TP in 2018: Staff #1 (CMS 209), Staff #2 (CMS 209), and Staff #5 (CMS 209). 2. An interview with Staff #2 (CMS 209) in an office area on 8/18/2018 at approximately 6:00 p.m. confirmed the TC failed to perform semi-annual competencies for the aforementioned TP. This deficiency contributed to the Immediate Jeopardy.