Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1034941	09/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lanier Interventional Pain Center Llc	2335 Limestone Overlook, Gainesville, 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 September 6, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assurance (QA) document review and laboratory consultant interview, the laboratory failed to document all general laboratory systems QA activities as required. Findings include: 1. QA document review revealed there was no QA documentation available at the time of survey for the following months in 2017: January, March, and April. 2. An interview with the laboratory consultant in a conference room on 9/6/18 at approximately 2 p.m. confirmed there was no QA documentation available for the aforementioned months in 2017.
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 calibration verification document review and laboratory consultant interview, the laboratory failed to perform calibration verification with the required frequency. Findings include: 1. BS-200 chemistry analyzer calibration verification document review revealed the laboratory failed to perform any calibration verifications in 2017. 2. An interview with the laboratory consultant in the conference room on 9/6/18 at approximately 12:10 p.m. confirmed there were no calibration verifications performed for the BS-200 chemistry analyzer in 2017.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and laboratory consultant (LC) interview, the laboratory director (LD) failed to delegate the TP competency performance to a qualified individual as required. Findings include: 1. TP document review revealed the 2018 initial and 6-month competency for Staff #1 (CMS 209) was performed by an unqualified individual due to lack of laboratory experience and education documentation. 2. The individual who performed the aforementioned competencies was not included on the CMS 209. 2. An interview with the LC in a conference room on 9/6/18 at approximately 2 p.m. confirmed there was no laboratory experience documentation nor education documentation for the individual who

	performed the aforementioned competencies. During the same interview, the LC confirmed the evaluator was not an employee of the facility and was not listed on the CMS 209.