Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2044488	07/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Roswell Pain Specialists, Llc	1300 Upper Hembree Road, Bldg 100, Suite B1, Roswell, 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 July 20, 2021. 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:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on document review and interview with the staff, it was determined the laboratory failed to document inspection of the Eyewash bottles as required. The Findings include: 1. The review of maintenance records revealed that the laboratory failed to document inspection on the Eyewash bottles, as required on a weekly basis, according to the procedure manual for 2019, 2020, and thus far 2021. 2. During an interview with the lab director and TP#2 (CMS-209) at 10:05 AM on 07/20/2021 during the lab tour, it was confirmed the laboratory failed to document inspection of the Eyewash bottles in 2019, 202 and 2021.
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 review of the laboratory procedure manual (SOP), quality assurance (QA) records, and interview with the laboratory director, the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Th findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems. Corrective actions and QA activities are not documented in the laboratory to reflect all phases of the QA policy in 2019, 2020 and 2021. 2. An interview with the laboratory director on 07/20/ 2021 at approximately 12:19 PM in the break room confirmed that the laboratory was not documenting corrective actions and QA activites in 2019, 2020 and 2021.
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 record review and laboratory director interview, the laboratory failed to record enviromental conditions as required by the Global BPC Biosed 240 Chemistry testing analyzer. The Findings include: 1. The temperature records review revealed that the laboratory failed to record room temperature, humidity and refrigerator temperatures as required in 2019, 2020 and 2021. 2. An interview the laboratory director on 07/20/ 2021 at approximately 12:30 PM in the break room confirmed no temperature logs for 2019, 2020 and 2021 were available at the time of survey.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Assurance(QA) manual review and interview with the staff, the Lab Director(LD) failed to review all QA documents on a monthly basis as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Quality Assurance (QA) documents review revealed the laboratory director, did not review

	quality assurance documents including all maintenance and temperature logs as required in 2019, 2020, and 2021. 2. During an interview with the lab director in the break room on 07/20/2021 at approximately 12:40 PM, it was confirmed the LD did not review QA documents as required in 2019, 2020 and 2021.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual (SOP), observation during the lab tour, and staff interview, the laboratory failed follow the policy for labeling specimens collected. Findings include: 1. Observation during the lab tour at 10:00 AM reveals 4 urine specimens on the lab counter to the right of the sink labeled with the patient's first and last name only. A second unique identifier was not on the labeled specimens. 2. Review if the SOP reveals the lab policy that specimens are to be labeled with two (2) unique identifying factors such as name, date of birth, or patient ID (identification) number. 3. Interviews with the laboratory director and TP # 2 (CMS 209) on 07/20/2021 in the laboratory at approximately 10:03 AM, confirmed the urine specimens were not labeled with two(2) unique identifiers.