Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D0891427	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Charleston Pain And Rehabilitation Center	1124 Sam Rittenberg Boulevard Suite 1, Charleston, SC	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: During an onsite recertification on 07/24/2018, based on instrument operator manual review, instrument maintenance record review and testing personnel interview, it was determined that the laboratory failed to document quarterly maintenance on the Pictus 400 toxicology instrument for twenty two of twenty two months reviewed (October 2016 through July 2018). Findings include: 1. Review of the Pictus 400 toxicology analyzer operator's manual on 07/24/2018 at 11:30am revealed that all operators should routinely perform scheduled maintenance to ensure optimum performance of the instrument including a quarterly optical filters cleaning, replacement of the distilled water aspiration tube, and cleaning of the distilled water reservior. 2. Review of the Pictus 400 toxicology analyzer maintenance logs on 07/24/2018 at 11:35am revealed that quarterly maintenance had not been documented for twenty two of twenty two months reviewed (October 2016 through July 2018). 3. Testing personnel confirmed during an onsite interview on 07/24/2018 at 1:00pm that the quarterly maintenance had not been performed for the reviewed months.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: During an onsite recertification survey on 07/24/2018, based on procedure manual review, toxicology quality control (QC) record review, and confirmation by testing personnel, the laboratory failed to verify the stated assay values of toxicology QC materials prior to testing for twenty two of twenty two months reviewed (October 2016 through July 2018). Findings include: 1. The laboratory procedure manual stated that upon changing toxicology control lots, the stated values of each level would be verified prior to use through repeat testing and comparison on different days. 2. Review of the laboratory's toxicology QC records revealed that the laboratory failed to verify the stated assay values of toxicology QC materials prior to testing for twenty two of twenty two months reviewed (October 2016 through July 2018). There was no corrective action for the missing lot verification available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 07/24/2018 at 1: 00 pm that the laboratory failed to verify the stated assay values of QC materials prior to testing.
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: During an onsite recertification survey on 07/24/2018, based on CMS 209 review, testing personnel record review, and testing personnel interview, the laboratory failed to document annual competency evaluations for 1 of 1 testing personnel responsible for moderate complexity toxicology testing for 1 of 2 years reviewed (2017). Finding include: 1. The laboratory listed 1 testing personnel for moderately toxicology complex testing on the CMS 209 on the day of the survey. 2. Review of testing personnel records revealed that employees 1 did not have a documented annual competency evaluation for the year 2017 available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 07/24/2018 at 1: 00pm that the laboratory failed to document an annual competency evaluation for 1 of 1 testing personnel responsible for moderate complexity toxicology testing for the year 2017.