Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2094484	08/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sweetwater Pain And Spine	10451 Double R Blvd, Reno, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 30, 2022. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
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 review of the Quality Assessment (QA) Policy, review of reference laboratory and corresponding laboratory reports compiled for QA activities, review of laboratory quarterly meeting minutes, and interview with technical consultant, the laboratory director failed to ensure that the established QA program was maintained to assure the quality of laboratory services provided. Findings include: 1. The Quality Assessment Policy was amended on 10/16/2020 and approved by the laboratory director on 11/01/2020 to include: "Additional items: (quarterly) 1) A mix of pos/neg screening reports will be evaluated vs the confirmation testing data issued by the reference lab. At minimum, 10 reports/quarter. 2) Lab meetings with director, technical consultant & testing personnel will be held and documented. This will constitute an opportunity to discuss ongoing lab operations and possible areas of improvement, as noted by any party present." 2. Review of the reference laboratory

	and corresponding laboratory reports compiled for the QA activity for 2021 and 2022 revealed that the laboratory failed to evaluate 10 reports quarterly to ensure that the screening test results correlated with the confirmatory test results. The incoming technical consultant confirmed the findings on 8/30/2022 at approximately 4:00 PM. 3. Review of the laboratory meeting minutes revealed that there was no documentation of quarterly meetings held in 2022. The laboratory provided the quarterly meeting minutes for 2021 by electronic mail on 8/31/2022. The laboratory performs approximately 30,000 toxicology tests annually.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of the training records for the technical consultant, review of laboratory quality control (QC) records, review of QC Problem Logs, review of the analyzer QC printouts for the Viva Pro-E chemistry analyzer, and interview with the technical consultant, the laboratory director failed to ensure that the technical consultant was trained on the chemistry analyzer to provide appropriate consultation and properly supervise the testing personnel. Findings include: 1. There were no training records for the previous technical consultant for the Viva Pro-E chemistry analyzer. 2. Review of the laboratory and analyzer QC records for 6 Acetyl Morphine (6AM) and the QC Problem Logs from January 2021 to August 2022 revealed that this analyte, more than any other analyte, experienced QC problems and there were several days when the test results could not be reported due to QC failure. No investigation or corrective actions were taken and documented, or additional instructions given to the testing personnel by the technical consultant, for the QC issues with 6AM beyond the recalibration steps the testing personnel took and documented to resolve the QC issues. 3. The incoming technical consultant confirmed the findings on 8/30/2022 at approximately 4:00 PM. The laboratory performs approximately 30,000 toxicology tests annually.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records for the Viva Pro-E chemistry analyzer and interview with the technical consultant, the technical consultant failed to investigate and resolve unacceptable quality control results for the

	level 4 control for 6-Acetyl Morphine (6AM). Findings include: 1. Review of the quality control records and the QC Problem Logs for 6AM from January 2021 through August 27/2022 revealed that the the testing personnel did not report results for 6AM on several days due to QC unacceptable QC results. On April 8, 2022, the testing personnel repeated the level 4 QC six times before the acceptable result was obtained. 2. The technical consultant who was responsible at that time, reviewed the 4 /08/2022 instrument printouts of the unacceptable QC results on 5/07/2022 and did not investigate to resolve the problem. No corrective action was taken and documented by the technical consultant. 3. The incoming technical consultant confirmed the findings on 8/30/2022 at approximately 3:00 PM. The laboratory performs approximately 30,000 toxicology tests annually.
D6073	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(4) Each individual performing moderate complexity testing must follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records for the Viva Pro-E chemistry analyzer, review of the laboratories policies and procedures, and interview with the technical consultant, the testing personnel failed to follow the laboratory's established corrective action policies and procedures when quality control results were unacceptable for the level 4 control for 6-Acetyl Morphine (6AM). Findings include: 1. Review of the quality control records and the QC Problem Logs for 6AM from January 2021 through August 27/2022 revealed that the the testing personnel did not report results for 6AM on several days due to QC unacceptable QC results. On April 8, 2022, the testing personnel repeated the level 4 QC six times, recalibrating the instrument twice, before the acceptable result was obtained. 2. The General Quality Control Policy, section 7, stated, "Corrective Action if Control Results are Not Acceptable (i.e. exceed +/- 2 SD, are rejected by Westgard rules, or do not produce the expected qualitative result): a. Rerun the same control material. b. Run fresh control material. c. Inspect analyzer for malfunctions. Check for clogs, leaks, crimped tubing. d. Verify correct reagent and reagent condition. Replace if appropriate. e. Select the appropriate remedy if the source of the problem is identified. (i.e. clean probe, replace lamp, other instrument repair, prepare fresh reagents and/or controls, etc.) f. Recalibrate if appropriate. Use a new calibrator lot when necessary. Also, consult with supervisory staff and/or manufacturer's help line as necessary. g. Consult with supervisory staff and/or manufacturer's help line for additional steps to follow. h. Request on-site service from manufacturer when all available solutions have not corrected the problem. i. Do NOT report patient results if QC is unacceptable. Use alternate methods or hold samples until the problem is resolved. Consult with supervisory staff to determine the most appropriate action. j. Supervisory staff may opt to approve results in certain circumstances of the specific incident. Obtain the signature of the approving supervisor before reporting results in these cases." 3. There was no documentation that the testing personnel alerted the technical consultant that the QC problems with 6AM may need to be investigated further and contact the manufacturer's help line for technical assistance. 4. The incoming technical consultant confirmed the findings during the survey on 8/30/2022 at approximately 3:00 PM. The laboratory performs approximately 30,000 toxicology tests annually.

D6075	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(6) Each individual performing moderate complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records for the Viva Pro-E chemistry analyzer, review of the laboratories policies and procedures, and interview with the technical consultant, the testing personnel failed to document all corrective actions taken when the 6 AM level 4 QC results were unacceptable. Findings include: 1. Review of the quality control records and the QC Problem Logs for 6AM from January 2021 through August 27, 2022 revealed that on April 8, 2022, the testing personnel repeated the level 4 QC six times, recalibrating the instrument twice, before the acceptable result was obtained. 2. The QC Problem Log recorded a single entry on 4/08/2022: "6 AM-Level 4-QC under range-Recalibrated; passed @ 0.0821." 3. Review of the analyzer printouts and testing personnel notes on the seven pages revealed that the QC had been repeated six times after the initial failure and the analyzer recalibrated twice. The log did not not record each corrective action step taken to obtain the acceptable QC result. With only one entry, it indicates that the instrument was recalibrated and QC result was acceptable after the single corrective action documented. 4. The incoming technical consultant confirmed the findings during the on-site survey on 8/30/2022 at approximately 3:30 PM. The laboratory performs approximately 30,000 toxicology tests annually.