| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 34D2130391 | 09/12/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Comprehensive Pain Consultants Of | 310 Overlook Road, Suite B, Asheville, NC | |

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 |
|---|---|
| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's procedures and review of 2018 and 2019 Daily Temperature/Humidity Checklists 9/12/19, the laboratory failed to ensure corrective action was taken and documented for freezer readings outside of acceptable limits. Findings: The laboratory procedure "Preparation of Calibration Stock Standards For All Panels, Except ETG/THC" states, 17.) Place all Calibration Stock Standards in the freezer. They are to remain below -20 degrees C(Celsius) when not in use...." Review of the laboratory's "Daily Temperature/Humidity Checklist" revealed an acceptable Freezer temperature range of -15 to -20 degrees C. The acceptable freezer temperature range is not consistent with the laboratory's procedure for storage of the calibration stock standard reagents. Instructions on the temperature/humidity checklist state, "*=error, corrective action required." Review of 2018 and 2019 temperature/humidity checklists revealed freezer temperatures were warmer than the limits of -15 to -20 degrees C on the following days with no corrective action documented: 1. Freezer #1: a. 1 of 7 days in March 2019 - 3/17. 2. Freezer #2: a. 6 of 11 days in December 2018 - 12/5, 12/7, 12/12, 12/13, 12/14, 12/28; b. 3 of 6 days in May 2019 - 5/9, 5/23, 5/31; c. 1 of 5 days in July 2019 - 7/23; d. 1 of 7 days in August 2019 - 8/23. |