Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2008259	09/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Pain Center Allentown	1146 S Cedar Crest Blvd, Allentown, PA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of testing personnel competency assessment records, review of the competency assessment policy and interview with the technical supervisor (TS), the laboratory failed to have a complete competency assessment policy and evaluate the competency of 1 of 1 clinical consultant (CC) from 2017 to the day of survey. Findings Include: 1. On the day of survey, 9/16/2019, the laboratory could not provide a complete competency assessment policy for the CC from of 2017 to the date of survey. 2. The laboratory could not provide competency assessments performed on the CC in 2017, 2018 and 2019. 3. The TS confirmed the finding above on 9/16/2019 around 9:40 am.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) policy, QA documentation, and interview with the technical supervisor (TS), the laboratory failed to follow their QA

	policy and document monthly quality assessment activities from September of 2017 to August of 2019 (6 of 24 months). Findings Include: 1. The Quality Management Policy, under Quality indicators, B, states "Quality indicators will be evaluated on a monthly basis ...." 2. On the day of survey, 9/16/2019, review of QA monthly activity records revealed, the following QA activities were not evaluated on a monthly basis from September of 2017 to August of 2019 (6 of 24 months): 3. In 2017: 1 of 4 months (December). 4. In 2018: 3 of 12 months (January, November and December). 5. In 2019: 2 of 8 months (January and February). 6. The TS confirmed the findings above on 9/16/2019 around 10:15 am.
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 records and interview with technical supervisor (TS), the laboratory failed to perform calibration verification on 1 of 1 Thermo Fisher Microgenesis MGC 240 analyzer used to perform urine toxicology screenings at least once every 6 months from 2018 to the date of survey. Finding Include: 1. On the day of survey, 9/16/2019, review of calibration verification records revealed, the laboratory did not perform calibration verification on 1 of 1 Thermo Fisher Microgenesis MGC 240 analyzer used to perform urine toxicology screening tests at least once every 6 months from 08/2018 to 06/2019. 2. Calibration Verification was performed on the Thermo Fisher Microgenesis MGC 240 analyzer on August of 2018 and on June of 2019. 3. Between 8/1/2018 to 6/1/2019, 65,936 patient specimen were run on the Thermo Fisher Microgenesis MGC 240 analyzer. 4. The TS confirmed the findings above on 9/16/2019 around 12:00 pm.