Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D1102618	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Pain & Headache Treatment Center	546 South Broad Street, Meriden, CT	

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
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 surveyor observation and staff interview the laboratory failed to ensure adequate safety measures are maintained for the safety of its personnel. Findings include: 1. Surveyor observation of the laboratory's testing area on 5/3/18 at 10:30 AM revealed the following: a. Three bulging water damaged ceiling tiles which were located above laboratory equipment and reagents. b. Five cloth chairs that cannot be properly decontaminated. 2. Staff interview with the laboratory director on 5/3/18 at 11:00 AM confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview it was revealed that testing personnel were not following laboratory policies and procedures for toxicology tests Findings include: 1. Record review of patient final test reports on 5/3/18 revealed patients were being reported as quantitative for Amphetamines(AMP), Cocaine Metabolite (COC), Heroin

	Metabolite (6-MAM), Methadone Metabolite (MTD) and Opiates (OP) tested on the Indiko initial screening instrument. 2. Record review of the Laboratory Procedure Manual on 5/3/18 revealed initial screening results tested on the Indiko instrument are reported as "positive" or "Negative". 3. Staff interview with the laboratory director on 5/3/18 at 11:00 AM confirmed the above. 4. The laboratory performs 12,5000 initial toxicology screening tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to take corrective actions when the humidity level exceeded the laboratory's acceptable limits. Findings include: 1. Record review of the laboratory's 2016 humidity log on 5/3/18 revealed the humidity level exceeded the laboratory's acceptable range of 20-80% on the following months. Documentation for trouble shooting or corrective actions was not available. a. January: 18 working days b. February: 11 working days c. March: 7 working days d. October: 1 working day e. November: 5 working days f. December: 9 working days 2. Staff interview with testing personnel #1 (TP#1) on 5/3/18 at 11:30 AM confirmed the above findings. TP#1 stated the laboratory has difficulty maintaining acceptable humidity levels in the winter season.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to investigate and take corrective action when quality control (QC) materials were out of acceptable limits. Findings include: 1. Record review of the laboratory's QC log for initial screening toxicology tests on 5/3/18 revealed the following QC materials were out of acceptable limits and documentation for trouble shooting or corrective actions was not available. a. Cocaine Low (Level-1) QC was out on 4/29/16. b. Cocaine High (Level-2) QC was out on 2/8/17. c. Cocaine Low (Level-1) QC was out on 2/20/17. d.

	Opiates and Amphetamines High (Level-2) QC was out on 2/20/17. 2. Staff interview with testing personnel #1(TP#1) on 5/3/18 at 11:30 AM confirmed the above findings. TP#1 stated he/she repeated failed QC but documentation of corrective action is not available. TP#1 further stated patient samples were tested on the above indicated days and documentation for patient impact is not available. 3. The laboratory performs 12,500 initial screening toxicology tests annually.