

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1084351	<b>(X3) Date Survey Completed</b> 01/03/2024
<b>Name of Provider or Supplier</b> Capitol Pain Institute, Pa	<b>Street Address, City, State</b> 5200 Davis Ln # B200, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed for an announced validation survey and found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control records, and interview, the laboratory failed to have a procedure in place to establish mean and standard deviation (SD) for their semi-quantitative controls Liquicheck Urine</p>

Toxicology Control for Amphetamines, Barbiturates, Benzodiazepines, Cocaine Metabolites, Methadone, Opiates, and Cannabinoids tested on the Beckman Coulter AU 480 for 12 of 12 months reviewed. Findings follow. A. Review of the laboratory's policies and procedures showed no procedure for establishing mean and standard deviations (ranges) on the Beckman Coulter AU 480 for Amphetamines, Barbiturates, Benzodiazepines, Cocaine Metabolites, Methadone, Opiates, and Cannabinoids. The procedure on establishing mean and standard deviation was requested on January 2, 2024 at 1555 hours but not provided. B. Review of the Lot to Lot Validation Form for the study on 11/07/2022 for the current lot of QC in use, Lot 71990 and Lot 72680 stated, "Study: Perform instrument maintenance and calibration. Then run the new lot as patient samples. Run the samples 4x/day for 5 days (n=20). Input the data below and calculate the mean, SD, and range (4SD). Update the mean, if necessary, in the AU instrument computer as per the instruction manual" and showed the following Calculated Limits: Negative Control Lot 71990 mean / SD(10%) / Range Amphetamines 702.55 / 70.2 / 562 - 842 Barbiturates 140 / 14 / 112 - 168 Benzodiazepines 138.95 / 14.0 / 111 - 166 Cocaine 216.45 / 21.6 / 173.3 - 259.7 Methadone 243.35 / 24 / 195 - 291 Opiates 170.1 / 17 / 136 - 204 Positive Control Lot 72680 mean/ SD(10%) / Range Amphetamines 1379.4 / 138 / 1103.4 - 1655.4 Barbiturates 379.7 / 38 / 304 - 456 Benzodiazepines 382.1 / 38 / 306 - 458 Cocaine 348.15 / 34 / 280.15 - 416.15 Methadone 383.5 / 40 / 303 - 463 Opiates 412.1 / 40 / 332 - 492 ". All units in ng/mL C. QC records were reviewed from April, May, July, August, and September 2023 and matched the laboratory's target mean and SD on the Control Summary Report. Review of the laboratory's Control Summary Report for 1 year's worth of data from 11/07/2022 to 11/07/2023 showed the expected (target) mean and 2SD [expected/target 1SD and calculated 10% columns added]: Negative Control Lot 71990 mean / 2SD / [1SD] / [10%] Amphetamines 750 / 200 / 100 / 75 Barbiturates 150 / 40 / 20 / 15 Benzodiazepines 150 / 40 / 20 / 15 Cocaine 225 / 50 / 25 / 22.5 Methadone 225 / 50 / 25 / 22.5 Opiates 225 / 60 / 30 / 22.5 Cannabinoids 27.5 / 20 / 10 / 2.75 Positive Control Lot 72680 mean / 2SD / [1SD] / [10%] Amphetamines 1300 / 200 / 100 / 130 Barbiturates 400 / 80 / 40 / 40 Benzodiazepines 400 / 80 / 40 / 40 Cocaine 400 / 80 / 40 / 40 Methadone 400 / 80 / 40 / 40 opiates 400 / 80 / 40 / 40 Cannabinoids 75 / 20 / 10 / 7.5 All units in ng/mL D. Review of the laboratory's Control Summary Report for 1 year's worth of data from 11/07/2022 to 11/07/2023 showed the calculated mean, 2SD, and %CV [calculated 1SD added] for 1 year historical data: Negative Control Lot 71990 mean / 2SD / [1SD] / %CV Amphetamines 706 / 65.9 / 32.95 / 7.34 Barbiturates 148 / 32.09 / 16.05 / 10.86 Benzodiazepines 141 / 22.04 / 11.02 / 7.8 Cocaine 220 / 17.39 / 8.70 / 3.95 Methadone 243 / 12.24 / 6.12 / 2.52 Opiates 168 / 35.24 / 17.62 / 10.5 Cannabinoids 26.97 / 8.93 / 4.47 / 16.55 Positive Control Lot 72680 mean / 2SD / [1SD] / %CV Amphetamines 1354 / 190 / 95 / 7.01 Barbiturates 383 / 39 / 19.5 / 5.14 Benzodiazepines 410 / 65 / 32.5 / 7.9 Cocaine 364 / 39 / 19.5 / 5.32 Methadone 393 / 30 / 15 / 3.84 opiates 411 / 59 / 29.5 / 7.14 Cannabinoids 71.3 / 9.43 / 4.72 / 6.61 All units in ng/mL NOTE: Amphetamines (negative control) [and the other drugs] was set at >10% SD. E. Interview with the technical consultant/technical supervisor on January 2, 2024 at 1555 hours acknowledged they established their own mean and SD, used a SD of 10% to calculate ranges, and verified the SD for Amphetamines was >10% in error, and was unable to find a procedure or reference for establishing SD at 10%.

**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 review of quality control records, patient testing query, and interview, the laboratory failed to evaluate all patient test results to the previous acceptable QC run when QC failed on the Beckman Coulter AU 480 for ethanol and the assay was calibrated for one of one events over a period of 5 months of testing. Findings follow. A. Review of QC from April, May, July, August, and September 2023 showed QC was out of range for ethanol on 8/01/2023 and the corrective action was to calibrate. B. Review of a query of patients tested for ethanol to the last successful QC run on 07/31/2023 showed 19 patients were tested as listed by accession number: 1. 112083 2. 112112 3. 112076 4. 112068 5. 112078 6. 112151 7. 112106 8. 112122 9. 112072 10. 112082 11. 112075 12. 112074 13. 112085 14. 112086 15. 112080 16. 112070 17. 112136 18. 112069 19. 112065. C. Interview with the technical consultant/technical supervisor on January 3, 2024 at 1050 hours confirmed it was not laboratory practice to evaluate to the last successful QC.

**D6168**

**TESTING PERSONNEL**  
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on review of the pre-survey paperwork, stability study, laboratory personnel records, and interview, the laboratory failed to employ testing personnel that met the educational requirements for one of five testing personnel performing high complexity testing in Toxicology. See D6171.

**D6171**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or

medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of the pre-survey paperwork, stability study, laboratory personnel records, and interview, the laboratory failed to ensure one of five testing personnel met the minimum education requirements for high complexity testing in Toxicology. Findings follow. A. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory designated one testing personnel performing moderate complexity testing. B. Review of the stability study for ethanol screening on the Beckman Coulter AU 480 showed it was a modified test system (high complexity). C. Review of laboratory personnel records for testing personnel #5 found a high school diploma. D. Interview of the technical consultant/technical supervisor on January 2, 2024 at 1515 hours acknowledged testing personnel #5 (as listed on the CMS form 209) was the testing person on the Beckman Coulter AU 480 for screening. Phone interview with the technical consultant/technical supervisor on January 8, 2024 at

1527 hours acknowledged the only thing that changed with the modified test system was the specimen handling, everything on the analyzer was the same, and confirmed testing personnel #5 did not qualify for high complexity testing.