Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1099480	06/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Center For Pain Of Montgomery , Pc, The	448 St Lukes Drive, Montgomery, AL	

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
D2111	TOXICOLOGY CFR(s): 493.845(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) Proficiency Testing (PT) records and an interview with the Technical Supervisor 2 (TS2), the laboratory failed to ensure PT results were submitted before the due date specified by CAP. This was noted for one of the three 2025 Urine Toxicology Events. The findings include: 1. A review of the CAP PT records revealed a score of 0 percent due to "Failure to participate" on the Urine Toxicology 2025 Event (UT-A 2025). 2. TS2 confirmed the above findings during the exit conference on 06-09-2026 at 3:30 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3)

	Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the Daily Temperature and Humidity logs, the BS-480 Mindray Operator's Manual and an interview with the Technical Supervisor 2 (TS2) and Testing Personnel 4 (TP4), the laboratory failed to document the corrective action when the humidity was outside the specified range according to manufacturer's acceptable limits. The surveyor noted the humidity was outside acceptable limits for 56 days out of 63 days of testing from January-March 2025. The findings include: 1. A review of the RT and Humidity logs revealed an incorrect range requirement for the humidity where the BS Mindray Chemistry analyzers were in operation. The incorrect range requirement was listed as (2 to 60) C. 2. A review of the BS-480 Mindray Operator's Manual revealed on page 1-34, section 1.5.3 Environmental Requirements, Operating environment, A) "Temperature: ..." B) "Relative humidity: 35 percent to 85 percent..." 3. According to TS2, the review of the patient test records revealed 1003 patients were performed when the humidity was outside the acceptable limits. 4. TS2 and TP4 confirmed the above findings during the exit conference on 06-09-2026 at 3: 30 PM.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour, a review of patient test records and an interview with the Technical Supervisor 2 (TS2) and Testing Personnel 1 (TP1), the laboratory failed to ensure in-date pH Detect Quality Control (QC) materials were utilized prior to patient testing. The expired QC materials were in use for seven of the nine days in June 2026. The findings include: 1. Direct observation of the refrigerated DRI pH-Detect QC materials during the laboratory tour revealed the following QC materials had expired on 05-31-2026, however, the staff continued to utilize these controls prior to patient testing from June 1-9, 2026. A) pH Detect 3.6 Control, Lot 75432266 B) pH Detect 7.0 Control, Lot 75432267 C) pH Detect 11.5 Control, Lot 75432269 2. According to the TS2, the review of the patient test records revealed 1003 patients were performed with the expired QC. 3. TS2 and TP1 confirmed the above findings during the exit conference on 06-09-2026 at 3:30 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the SCIEX Triple Quad 4500 MD analyzer maintenance records,

	the SCIEX 4500 Series System User Guide, and interview with the Technical Supervisor 2 (TS2) and Testing Personnel 1 and 2 (TP1, TP2), the laboratory failed to document the maintenance as per manufacturer's instructions. The surveyor noted there was no documentation of the daily, weekly and annual maintenances for approximately 24 of the 24 months reviewed from June 2024 through June 2026. The findings include: 1. A review of the SCIEX Triple Quad 4500 MD analyzer maintenance records revealed no documentation of the required daily, weekly and annual maintenances for 24 months. 2. A review of the SCIEX Triple Quad 4500 MD Series System User Guide revealed on page 37 the following maintenance requirements. A) "System, daily, inspect for leaks..." B) "Curtain Plate, daily, clean..." C) "Roughing pump oil, weekly, inspect the level..." D) "Roughing Pump oil, annually..." 3. TS2, TP1 and TP2 confirmed the above findings during the exit conference on 06-09-2026 at 3:30 PM.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on reviews of the MindRay BS 480 Chemistry analyzer calibration records, review of the Policy and Procedure (P&P) Manual and interviews with the Technical Supervisor 2 (TS2) and Testing Personnel 4 (TP4), the Laboratory Director (LD) failed to document the changes in procedure for bi-annual Calibration-Verification (C-V). The surveyor noted no documentation of the revised C-V procedure from the date of the last survey, 05-21-2024, to the date of the current survey, 06-09-2026. Findings Include: 1. A review of the MindRay BS 480 Chemistry analyzer C-V records revealed a lack of C-V performed for the following schedules. a) Second C-V in 2024 b) First and second C-Vs in 2025 c) First C-V in 2026 2. A further review of the calibration records revealed the laboratory had switched to 3 or more calibrators for the assays tested on the MindRay BS 480 analyzers on 06-02-2025. However, there was no documentation on the P&P Manual that the LD had revised the C-V procedure. 3. TS2 and TP4 confirmed the above findings during the exit conference on 06-09-2026 at 3:30 PM.
D6090	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(ii) (e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) Proficiency Testing (PT) records and an interview with the Technical Supervisor 2 (TS2), the Laboratory Director (LD) failed to ensure PT results were submitted before the due date specified by CAP. This was noted for one of the three 2025 Urine Toxicology Events. The findings include: 1. A review of the CAP PT records revealed a score of 0 percent due to "Failure to participate" on the Urine Toxicology 2025 Event (UT-A 2025). No

	documentation the laboratory performed self-evaluation for the event that it failed to participate. 2. TS2 confirmed the above findings during the exit conference on 06-09-2026 at 3:30 PM.