Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1099480	10/22/2020
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) proficiency testing reports and an interview with Testing Personnel (TP) #1, who is also the laboratory manager, the surveyor determined the laboratory staff failed to rotate the analyses of proficiency testing samples, between the two employees trained to perform moderate complexity Chemistry testing. This affected six of six proficiency testing events (2018, 2019 and 2020), reviewed by the surveyor. The findings include: 1. Upon tour of the laboratory on 10/22/2020 at 9:15 AM, TP #1 identified analysis of urine samples for drug screens (Toxicology) on the Siemens Viva E as the only testing (moderate complexity) performed in the laboratory. TP #1 identified a second testing personnel (TP #2), who also analyzes patient specimens on this instrument. TP #2 was listed on the Laboratory Personnel Form (CMS #209). 2. A review of the attestation statements for Toxicology testing for 2018 - 2020 revealed TP #1 had signed all of the statements, attesting to the analyses of the proficiency testing samples for all events. 3. In an interview on 10/22/2020 at 2:15 PM, TP #1 stated TP #2 had been trained in November of 2017, and confirmed TP #2 periodically test patient samples. When the surveyor inquired of who runs the proficiency testing (PT) specimens, TP #1 stated she ran all of the PT specimens, because she is the person who has been doing the testing for a long time.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation records for an Oxycodone procedure added to the Siemens Viva E in October of 2020, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to review and approve the addition of the procedure to the laboratory's test menu, prior to staff testing patient samples and reporting the results. This affected one of one new test procedure, added to the menu, since the previous survey on 02/06/2018. The findings include: 1. On tour of the laboratory on 10/22/2020 at 9:15 AM, TP #1 stated a new Oxycodone procedure was added, since the previous survey in 2018. 2. A review of the validation records for the new Oxycodone procedure revealed a comparison study was performed on 10/15/2020 - 10/16, with testing nine samples on two different instruments, for verification of precision and accuracy (The laboratory reports qualitative results). 3. The validation records (precision and accuracy) were not signed by the Laboratory Director, nor the Technical Consultant. The approval of a validation study may be evidenced by the Laboratory Director's signature, an effective date, and a summary of conclusion of the data. 4. In an interview on 10/22/2020 at 2:15 PM, TP #1 stated Siemens changed the Oxycodone procedure, so the laboratory performed a validation for the new drug, with the assistance of the manufacturer's technical specialist. TP #1 further stated the validation occurred a few days prior to the survey, and she emailed the summary of the validation study to the Laboratory Director a couple of days before the survey. When asked when patient testing began, using the new procedure, TP #1 replied the patient testing and reporting began the next work day (confirmed as October 19), after the study was done. The Laboratory Director had not signed the validation study, indicating use of the new procedure in the laboratory for patient testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the CMS form #209 (Laboratory Personnel Form), a review of the laboratory's competency assessments, and an interview with Testing Personnel (TP) #1, the surveyor determined the Technical Consultant failed to ensure TP #1's competency was assessed in 2019 and 2020. This affected one of one testing personnel, who performs moderate complexity testing and has been performing testing for greater than a year. The findings include: 1. The surveyor requested the laboratory complete the Laboratory Personnel Form. TP #1 was listed on the form and identified herself on tour as the laboratory manager and primary testing personnel. 2. A review of the training and competency records revealed a "Laboratory Personnel

	Evaluation" with TP #1's name, with the date 1/21/2019, and another dated 1/20/2020. The laboratory director's signature was stamped at the bottom of each form. The forms had ten possible areas of consideration for assessment, with instructions at the top of the form to mark yes, no or not applicable. The areas for assessment were left blank. 3. In an interview on 10/22/2020 at 2:15 PM, the surveyor inquired of the frequency of visits/consultation of the Laboratory Director (LD) and the Technical Consultant (TC). TP #1 stated the LD comes about every two to three months and reviews "anything" the testing personnel needed a sign-off. She later described these items as proficiency testing records and environmental controls. TP #1 stated the TC visited every two to three months, prior to the pandemic, but had not come since the beginning of the pandemic. TP #1 further stated the TC would review proficiency testing, patient results, maintenance and environmental concerns. When asked who assessed her competency, TP #1 replied the laboratory director usually goes over it with her, and he was last there on September 30, 2020. TP #1stated the LD had not signed the competency assessments, but he reviewed the evaluation form with her. When asked about the rubber stamp for the LD's signature, TP #1 stated she was the only person who uses the stamp. The surveyor observed the rubber stamp used for the personnel evaluations. The surveyor cautioned the testing personnel on the use of the rubber stamp.