Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1099480	02/06/2018
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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the CAP (College of American Pathologists) Proficiency Testing (PT) records and an interview with the Laboratory Supervisor (also the Testing Personnel), the surveyor determined the laboratory failed to retain complete records for one of two 2016 surveys. The findings include: 1. A review of the CAP Proficiency Testing records revealed the laboratory had failed to retain the program report forms, instrument printouts, signed attestation statement or signed results review sheet for the 2016 DMPM-A (Drug Monitoring for Pain Management) survey. 2. In an interview on 2/6/2018 at 10:25 AM, the Laboratory Supervisor was asked about the missing PT records, however no additional records were provided during the survey. Thus the above noted findings were confirmed. .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2016-2017 CAP (College of American Pathologists) Proficiency Testing records and an interview with Laboratory Supervisor (also the Testing Personnel), the surveyor determined the laboratory failed to document reviews of two of two of the returned 2016 survey results evaluations, and failed to document investigation and corrective action for two of two 2017 surveys with unacceptable results. The findings include: 1. A review of the CAP Proficiency

	Testing records revealed no documentation of review of the returned scores and results evaluations for the 2016 DMPM (Drug Monitoring for Pain Management) Event-A and -B surveys. 2. A review of the 2017 DMPM CAP surveys revealed the following results: A) DMPM-A: Specimen 01-Oxycodone Unacceptable B) DMPM-B: Specimen 06-Cannabanoids Unacceptable There was no documentation of investigation to determine the cause for the unacceptable results, or implementation of corrective action to prevent recurrence. 3. In an interview on 2/6/2018 at 10:25 AM, the Laboratory Supervisor was asked for documentation of review and corrective actions for the above surveys. The Supervisor stated she had not realized this was required, thus the above noted findings were confirmed. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of the maintenance procedures in the Operator's Manual for the Viva-E (used for urine toxicology testing), laboratory maintenance records, and an interview with the Laboratory Supervisor (also the Testing Personnel), the surveyor determined the laboratory failed to perform and document the weekly, monthly and quarterly maintenance with the frequency required by the manufacturer for two years (since the previous survey on 2/25/2016). The findings include: 1. A review of the maintenance logs revealed a laboratory developed general maintenance sheet for procedures performed each days including the maintenance required for the Viva-E. There were no logs used for documentation of Viva-E maintenance performed less frequently. 2. A review of section 6-1 Maintenance procedures on page 6-2 in the Viva-E Operator's Manual, revealed the following: "...Weekly Perform needle rinse procedure: clean the sample and reagent needle with hypochlorite solution. Check syringes for large air gaps and leakage; clean and replace syringes if necessary..." "... Monthly Clean water and waste container(s) with 0.1 mol/l NaOH [0.1 moles per liter Sodium Hydroxide]. Afterwards rinse several times with water. ...Shut down the computer and turn the instrument off. Switch the instrument and computer on to restart the analyzer." "Quarterly Replace mixer belts. Replace water filter. Replace drying block on wash arm." 3. During an interview on 2/6/2018 at 12:20 PM, the above procedures were reviewed with the Laboratory Supervisor who stated the Siemens technical representative did some of the above maintenance during the service calls; he had also told her some of the procedures did not need to be performed as often as directed in the manual. The surveyor explained if the manufacturer had changed their maintenance procedures, they should specify this in writing, and personnel should be re-trained. The Supervisor was then asked if she had performed and documented any of the weekly, monthly or quarterly maintenance; the Supervisor stated she performed some of the above maintenance, but did not document it. Thus the above noted finding were confirmed. .
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 installation and validation documentation for the Siemens Viva-E analyzer (used for qualitative Urine Toxicology testing) and an interview with the Laboratory Supervisor (also the Testing Personnel), the surveyor determined the previous Laboratory Director failed to document his review and approval of the initial validation procedures as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the installation and validation records for the Siemens Viva-E analyzer revealed no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed on 4/13/2016. The Testing Personnel began using this analyzer for Urine Toxicology testing on patient samples on 4/20/2016. 2. During an interview and review of these records on 2/6/2018 at 11:00 AM, the Laboratory Supervisor confirmed she was unable to find any documentation the data had been reviewed or approved. SURVEYOR:Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor