

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2035674	(X3) Date Survey Completed 02/02/2018
Name of Provider or Supplier Pain Institute Of Nashville Plc	Street Address, City, State 1849 Madison St Suite D & Suite F, Clarksville, TN	
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
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Intakes: TN00043185 Citation Number One: Based on review of the CMS CLIA application and Survey Summary (0096D) Report, 2017 College of American Pathologist (CAP) Proficiency testing records, patient test records, and interview with testing personnel number one, the laboratory failed to perform testing on operating days and hours indicated on the CMS 0096D report for 1 of 3 patients and 3 of 3 proficiency testing events in 2017. The findings include: 1. Review of the CMS 0096D report revealed the following operating days and hours: Monday through Thursday, 8:00 am to 4:00 pm each day. 2. Review of the laboratory's 2017 CAP proficiency testing records revealed the following: 2017 event 1 reported on 3-17-17 (Friday), 2017 event 2 reported on 7-28-17 (Friday), 2017 event 3 reported on 10-20-17 (Friday). 3. Review of 3 patient test reports revealed the testing performed on hours not indicated on the CMS 0096D report for this laboratory as follows: Patient #2 reported on 12-6-17 (Wednesday) at 05:37 pm. 4. Interview with testing personnel</p>

number one on January 11, 2018 at 4:30 pm confirmed the laboratory failed to perform testing on days and hours indicated on the CMS 0096D for 3 of 3 proficiency testing events and 1 of 3 patients in 2017.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with testing personnel number one, the laboratory director failed to ensure the environmental conditions provide employees a safe break area free from biological hazards. The findings include: 1) Observation of the laboratory on January 11, 2018 at 1:00 pm revealed food and drink in the testing area of the laboratory, on a table next to the testing instrument. 2) Observation of the laboratory on February 2, 2018 at 11:15 a.m. revealed a designated break area containing a coffee maker with accessories. Personnel from the pharmacy next door walked into the laboratory and poured a cup of coffee during this survey. 3) Interview on January 11, 2018 at 4:30 pm with testing personnel number one confirmed food and drink was in the testing area of the laboratory. 4) Interview on February 2, 2018 at 12:30 p.m. with testing personnel number one confirmed the laboratory and pharmacy next door share the coffee break area in the laboratory which is not an area free from biological hazards. The laboratory director failed to provide a break area free from biological hazards.