

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2106550	(X3) Date Survey Completed 02/02/2018
Name of Provider or Supplier John Stanton Md Pc	Street Address, City, State 1849 Madison St Ste D, 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: Citation Number One: Based on review of the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendment (CLIA) application and Survey Summary (0096D) Report, the laboratory's 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 proficiency testing events in 2017 and 3 of 3 patients in 2017 and 2018. The findings include: 1. Review of the CMS 0096D report revealed the following operating days and hours: Friday 12:00 pm to 10:00 pm. 2. Review of the laboratory's 2017 CAP proficiency testing records revealed the following: 2017 event 2 on batch for 7-27-17 (Thursday). 3. Review of 3 patient test reports revealed testing performed on hours not indicated on the CMS 0096D report for this laboratory as follows: Patient #1 reported on 12-18-17 (Monday) at 08:51 pm, patient #2 reported on 12-18-17 (Monday) at 08:51 pm, Patient #3 reported on 1-9-18 (Tuesday) at 03:38 pm. 4. Interview with testing personnel number one on January 11, 2018 at 4:30 pm confirmed the laboratory failed</p>

to perform testing on days and hours indicated on the CMS 0096D for 1 out of 3 proficiency testing events and 3 of 3 patients in 2017 and 2018. Citation Number Two: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendment (CLIA) application and Survey Summary (0096D) Report, the laboratory instrument maintenance records and interview with testing personnel number one, the laboratory director failed to ensure the instrument maintenance was performed during the laboratory operating days and hours and failed to ensure each laboratory located at this address maintain separate records. The findings include: 1) Observation of the laboratory on January 11, 2018 at 10:30 a.m. revealed one AB Sciex API 4000 instrument in use for toxicology testing. 2) Review of the CMS CLIA 96 report revealed the days and hours of operation are Friday 10 pm to 12 pm. 3) Review of the laboratory instrument maintenance records revealed on June 6, 2017 (Tuesday), May 29, 2017 Tuesday) maintenance was performed. 4) Interview on February 2, 2108 at 11:25 a.m. with testing personnel number one confirmed the instrument was performing calibrations for this laboratory during hours that belonged to the third laboratory. And, that the maintenance was performed on dates the laboratory was not operational and failed to ensure each laboratory maintain separate records.

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 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. 2) 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.