

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D0302002 | (X3) Date Survey Completed 12/20/2018 |
| Name of Provider or Supplier Dr Tai's Clinic | Street Address, City, State 2401 Viking Drive, Jasper, 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 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the AAFP (American Academy of Family Physicians) Proficiency Testing (PT) records, personnel records, and an interview with Testing Personnel #4, the laboratory failed to ensure proficiency testing samples were rotated between all personnel who routinely performed moderate complexity testing on patients; and the laboratory further failed to ensure PT samples were tested during times when regular patient testing occurred. This was noted on six of seven surveys reviewed. The findings include: 1. A review of AAFP attestation statements revealed Testing Personnel (TP) #4 had performed all the testing on six out of seven surveys performed from 10/19/2016 to 10/7/2018 (the most recent survey). One survey (Survey B-2018) had been performed by TP #1. 2. A review of the personnel files revealed TP #1 was full time, and had been qualified to perform moderate complexity testing since the previous survey (on 10/20/2016). (Two other testing personnel were recently hired in 2018.) 3. A review of instrument printouts of the PT results further revealed the the PT samples were run in the evenings after the clinic was closed at 5:00 PM. 4. During an interview with TP #4 on 12/20/2018 at 11:30 AM, the surveyor explained the CLIA requirement of integrating PT samples in with the normal patient workloads, and ensuring PT specimen testing was rotated among all personnel who performed patient testing. Testing Personnel #4 confirmed she had performed six out of seven surveys herself after hours to prevent interruptions in patient care and testing. Thus the above noted findings were confirmed. .</p> |
| D5445 | CONTROL PROCEDURES |

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the IQCP (Individualized Quality Control Plan), the Quality Control (QC) records and the patient logs for the Affinion AS 100 (used for urine Microalbumin/creatinine [ACR] testing), and interviews with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed and documented every 30 days of patient testing as per the IQCP which was implemented after the previous survey in 2016. The findings include: 1. A review of the IQCP for the Affinion AS 100 (used for urine Microalbumin/creatinine or "ACR" testing) revealed a QC Plan which specified two levels of QC should be performed and documented every 30 days of patient testing, and with each new lot number of reagent cartridges, as per manufacturer's instructions. 2. A review of the November 2016 thru December 2018 Affinion QC data log revealed QC had been performed most months (except December 2017 and April 2018), however the QC testing exceeded the 30 day frequency specified in the IQCP thirteen times in the review period. 3. During an interview on 12/20/2018 at 2:15 PM, the surveyor and TP #1 reviewed the QC Plan in the IQCP, and the dates the testing personnel had performed the ACR QC. TP #1 realized the laboratory had failed to follow the manufacturer's instructions and their IQCP by running the QC "Monthly", which often exceeded the required 30 day QC performance frequency. 4. A review of the November 2016 thru December 2018 Affinion ACR patient log revealed thirteen periods exceeding the required 30 day QC performance frequency when 339 patient tests were run, as follows: A. 12/16 thru 12/29/2016: 29 patients tested B. 2/5 thru 2/16/2017: 26 patients tested C. 3/19 thru 3/28/2017: 27 patients tested D. 8/11 thru 8/24/2017: 38 patients tested E. 9/24 thru 9/28/2017: 13 patients tested F. 11/23 thru 11/28/2017: 6 patients tested G. 12/29/2017 thru 1/3/2018: 10 patients H. 2/2 thru 2/12/2018: 25 patients tested I. 3/15 thru 3/28/2018: 34 patients tested J. 4/23 thru 5/14/2018: 26 patients tested K. 6/14 thru 6/28/2018: 29 patients tested L. 8/4 thru 8/19/2018: 40 patients tested M. 10/12 thru 10/24/2018: 36 patients tested 5. During the exit summation on 12/20/2018 at approximately 3:10 PM, the above noted dates and number of patients affected were reviewed and confirmed with TP #1 with the Clinic Supervisor present. Surveyor ID#32558 Licensure and Certification Surveyor