Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0302002	06/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dr Tai's Clinic	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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with Testing Personnel #1, the Laboratory Director failed to approve the Procedures being used in the Laboratory by signature. The findings include: 1. A review of the Procedure for Drawing Blood, Quality Assurance Program, and User Manuals for Afinion and Cell-Dyn Emerald revealed the Laboratory Director had not approved Procedures by indication of signature. 2. During an interview on 06/22/2021 at 2:00 PM, Testing Personnel #1 confirmed the Procedures located during the survey were not signed by the Laboratory Director.
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 Afinion AS 100 (used for urine Microalbumin/Creatinine (ACR) testing), and an interview with Testing Personnel #1, 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. This was noted three times from January 2019 to June 2021. This is a repeat citation. The findings include: 1. A review of the IQCP for the Afinion AS 100 (used for urine Mircoalbumin /Creatinine) 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 January 2019 to June 2021 Afinion QC data log revealed QC had been performed most months (except May 2019, July 2019, and October 2019), however the QC testing exceeded the 30 day frequency specified in the IQCP during those months. a) QC was performed on 04/03/2019, next QC run was 05/07/2019 (only level 2 passed on this day) and 05/09/2019 (both levels passed) during this time 3 patients were performed. b) QC was performed on 06/12/2019, next QC run was 08/02/2019 during this time 40 patients were performed. c) QC was performed on 09/04/2019, next QC run was 10/02/2019 (only level 1 passed on this day) and 10/14/2019 (both levels passed) during this time 21 patients were performed. 3. During an interview on 06/22 /2021 at 11:45 AM, Testing Personnel #1 confirmed the laboratory failed to follow IQCP and failed to verify that QC passed on 05/07/2019 and 10/02/2019.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. 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 an interview with Testing Personnel #1, the Laboratory Director failed to ensure the IQCP was maintained to identify failures in quality control. The findings include: Refer to D5445.