Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1103235	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Deng Family Medicine & Careu	8900 Se 15th St, Midwest City, OK	

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
D0000	The recertification survey was performed on 03/23/2022. The findings were reviewed with the laboratory manager and laboratory director at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director or designee failed to sign a proficiency testing attestation statement for one of 15 events. Findings include: (1) The surveyor reviewed 2020 and 2021 proficiency testing records and identified the following for one of five events: (a) Second 2021 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director or designee and the testing person. (2) The surveyor reviewed the findings with the laboratory manager who stated on 03/23/2022 at 12:20 pm, the attestation statement had not been signed by the testing person and laboratory director or designee as shown above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's storage instructions, and interview with the laboratory manager, the laboratory failed to ensure the hematology analyzer was being stored according to manufacturer's humidity requirements for three of four months; and failed to ensure collection devices were stored according to manufacturer's storage requirements for four of four months Findings include: HUMIDITY (1) On 03/23/2022 at 11:40 am, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (2) On 03/23/2022, the surveyor reviewed the manufacturer's humidity requirements for the analyzer, which was 30% to 80%; (3) On 03/23/2022, the surveyor reviewed four months (November 2021 through February 2022) of laboratory humidity records and identified for three of four months the humidity readings were documented as less than 30% as follows: (a) December - 2 of 31 days (days 2,13); (b) January - 13 of 31 days (days 3,5,6,7,11,12,17,19,20,21,24,26,28) (b) February - 8 of 28 days (days 7,8,11,14,22,24,25,28). (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 03/23/2022 at 03:55 pm the analyzer had been stored at a humidity below the manufacturer's requirement as indicated above. ROOM TEMPERATURE (1) On 03/23/2022 at 11:40 am, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer; (b) Free T4 (Thyroxine), TSH (Thyroid Stimulating Hormone), SHBG (Sex Hormone Binding Globulin), Testosterone, and Vitamin D were performed on the Beckman Coulter Access 2 analyzer. (c) Blood collection tubes were stored in the laboratory draw room. (2) The surveyor reviewed the manufacturer's environmental requirements for the blood collection tubes, which required a room temperature 4-25 degrees C (Celsius). The following were examples of blood collection tubes stored in the rooms: (i) BD Vacutainer K2 EDTA (300 tubes of lot# 3919231); (ii) BD Vacutainer Tiger Top SST (300 tubes of lot# 1312504). (3) On 03/23/2022, the surveyor reviewed four months (November 2021 through February 2022) of draw room temperature records and identified for four of four months the temperature readings were documented as greater than 25 degrees C as follows: (a) November - 3 of 30 days (1,2,16) (b) December - 8 of 31 days (days 1,3,9,13,14,15,20,30); (b) January - 4 of 31 days (days 3,12,19,28) (b) February - 2 of 28 days (days 11,14). (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 03/23/2022 at 04:10 pm the blood collection tubes had been stored at a temperature above the manufacturer's requirement as indicated above.
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 records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of five quarterly maintenances; and failed to follow the weekly maintenance procedures for two of seven months. Findings include: SYSMEX XP-300 (1) On 03/23/2022 at 11:40 am, the laboratory manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 analyzer. (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. (a) Quarterly (i) Clean SRV (3) The surveyor reviewed maintenance records for 13 months (January 2021 through February 2022) and identified the following: (a) There was no evidence the quarterly maintenance had been performed (i) Between 07 /26/2021 and 02/08/2022 (missing the 4th quarter of 2021) (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 03/23 /2022 at 01:34 pm, the maintenance had been performed but not documented. BECKMAN COULTER ACCESS 2 (1) On 03/23/2022 at 11:45 am, the laboratory manager stated the following to the surveyor: (a) Free T4 (Thyroxine), TSH (Thyroid Stimulating Hormone), SHBG (Sex Hormone Binding Globulin), Testosterone, and Vitamin D were performed on the Beckman Coulter Access 2 analyzer. (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. (a) Weekly Maintenance (i) Clean Instrument Exterior (ii) Inspect Liquid Waste Bottle (iii) Check Waste Filter Bottle (iv) Inspect /Clean Aspirate Probes (v) Run System Check (3) The surveyor reviewed maintenance records for seven months (June 2021 through December 2021) and identified the following: (a) There was no evidence the weekly maintenance had been performed (i) Between 06/11/2021 and 06/23/2021 (ii) Between 08/27/2021 and 09/09 /2021 (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 03/23/2022 at 01:58 pm, the maintenance had been performed but not documented.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report and interview with the laboratory manager, the laboratory failed to provide normal reference intervals for one of one urine sediment test report. Findings include: (1) On 03/23/2022 at 11:55 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed urine sediment testing. (2) The surveyor reviewed one test report for Patient #93840 tested on 03/18 /2022 at 09:57 am. The report did not include a normal reference range; (3) The report was reviewed with the laboratory manager, who stated on 03/23/2022 at 03:54 pm the patient report did not include a normal reference range.