Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1103235	01/03/2024
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 01/03/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and the laboratory manager during an exit conference performed at the conclusion of the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to follow their policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of three competencies performed during the review period of November 2021 through the current date. Findings include: (1) A review of records and interview with the laboratory manager on 01/03/2024 at 01:00 pm confirmed the laboratory director performed competencies for the technical consultant, based on job responsibilities, at least annually; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of November 2021 through the current date identified competencies, based on job responsibilities, had not been documented as performed after 11/22/2022 for one of one person listed as technical consultant on Form CMS-209; (3) The findings were reviewed the laboratory manager who stated on 01/03/2024 at 01:20 pm, the competency for the technical consultant had not been performed in 2023 as stated above.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for 12 of 12 lot numbers used during the review period of 01/04/2023 through 10/06/2023. Findings include: (1) On 01/03/2024 at 12:30 pm, the laboratory manager stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 hematology analyzer; (b) Three levels of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of the Laboratory Procedure Manual (book 1 of 2), policy No. 5.20, subject: Hematology Quality Control, section II. "Setting up New Lot Quality Control" stated the following: (a) "4. Run all 3 levels of QC twice a day for 5 days (total of 10 runs). a. Note: always run the current active QC after running the new QC. This must be done before patients are performed." (b) "5. After the 5 days, use the running means of the 10 runs as the new set mean for each level of QC. Check that these values of within the package insert range of mean." (c) "6. Once new mean is established. New QC is ready to use." (3) A review of records for 12 control lot numbers used from 01/30/2023 through 10/06/2023 identified no documentation to prove the following lot numbers had been implemented per policy: (a) Lot #23620710, 23620711, and 23620712 used from 01/30/2023 through 03/31/2023; (b) Lot #30810710, 30810711, and 30810712 used from 04/03/2023 through 06/28/2023; (c) Lot #31650710, 31650711, and 31650712 used from 06/29/2023 through 09/20/2023; (d) Lot #32490710, 32490711, and 32490712 used from 09/21/2023 through 10/06/2023. (4) The findings were reviewed with the laboratory manager who stated 01/04/2024 at 1:45 pm, the laboratory did not follow their written policy.
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 observation and interview with the laboratory manager, the laboratory failed to ensure five of five types of blood collection tubes were stored as required by the manufacturer, in a room denoted as the Dexa draw room. Findings include: (1) Observation of the draw room and interview with the laboratory manager on 01/03/2024 at 10:25 am, identified the following: (a) 6 BD Vacutainer SST tubes, lot #

	3160661, storage temperature of 4-25 degrees (C) centigrade; (b) 3 BD Vacutainer SST tubes, lot # 3153061, storage temperature of 4-25 degrees C; (c) 3 BD Vacutainer K2EDTA 7.2mg, lot # 322731, storage temperature of 4-25 degrees C; (d) 2 BD Microtainer brand tubes, lot # 2301273, storage temperature of 4-25 degrees C; (e) 2 BD Microtainer brand tubes K2EDTA, lot # 2071821, storage temperature of 4-25 degrees C. (2) Interview with the laboratory and the laboratory manager on 01/03 /2024 at 10:30 am confirmed the laboratory was not monitoring the temperature of the draw room.
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 instruction manual, and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Sysmex XP-300 hematology analyzer during the review period of January 2023 through November 2023. Findings include: (1) On 01/03/2024 at 09:25 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 hematology analyzer; (2) A review of the "Cleaning and Maintenance" on section 12 of the manufacturer's instructions manual required the following maintenance procedures: (a) Weekly "Clean SRV tray" (b) Monthly "Clean RBC and WBC Transducer; Clean Waste Chamber" (b) Every 3 months "Clean SRV" (3) A review of maintenance logs from January 2023 through November 2023 identified maintenance had not been documented as performed for the following: (a) Weekly: i. Between 06 /28/2023 and 07/14/2023 (b) Monthly: i. Between 06/08/2023 and 08/14/2023 (c) Every 3 months: i. Between 02/27/2023 and 07/14/2023 (4) The records were reviewed with the laboratory manager who stated on 01/03/2024 at 1:45 pm, maintenance procedures had not been documented as performed as stated above.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly for two of two function checks performed from January 2022 through the current date. Findings include: (1) On 01/03

	/2024 at 10:00 am, the laboratory manager stated the following: (a) The laboratory performed urine microscopic testing; (b) The urine specimens were processed at a speed of 2000 rpm (revolutions per minute) for 5 minutes using the Select Medical Products PSS 602 centrifuge. (2) A review of the laboratory policy and procedure manual identified no evidence of a function check protocol that defined the frequency of the urine centrifuge speed and timer checks and the acceptable limits for the checks; (3) Interview with the laboratory manager on 01/03/2024 at 01:10 pm, confirmed the laboratory did not have a written function check protocol but the centrifuge speed was checked at least twice annually; (4) A review of records from January 2022 through the current date identified the following: (a) 06/30/2023 - Although the speed had been checked at 2107 rpm, there was no documentation the timer had been checked. In addition, there was no documentation if the result of the speed check was acceptable; (b) 12/18/2023 - Although the speed had been checked at 2072 rpm, there was no documentation the timer had been checked. In addition, there was no documentation if the result of the speed check was acceptable; (c) There was no documentation the centrifuge speed and timer had been checked prior to 06/30 /2023. (5) The findings were reviewed with the laboratory manager who stated on 01 /03/2024 at 01:15 pm, the laboratory did not have a written function check protocol for the urine centrifuge and did not ensure the urine centrifuge was functioning properly as shown above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, QC (quality control) package inserts, and interview with the laboratory manager, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for TSH (Thyroid Stimulating Hormone) testing for three of three months reviewed from September through November 2023. Findings include: (1) On 01/03/2024 at 09:50 am, the laboratory manager stated the following: (a) The laboratory performed TSH testing using the Beckman Coulter Access 2 analyzer; (b) Two levels of Bio-Rad Liquichek Immunoassay Plus Control materials were performed each day of patient testing. (c) When new lot numbers of control materials were put into use, the laboratory established means and two SD (Standard Deviation) ranges for each analyte. (2) A review of the manufacturer's instruction (package insert) for the control materials stated, "The mean values and the corresponding +/-3SD ranges in the Assignment of Values Data Charts were derived from replicate analyses and are specific for this lot of product. Data from Unity Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or

	independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides"; (3) A review of QC records for two lot numbers of control materials used during the review period of 09 /01/2023 through 11/30/2023 identified the following: (a) Level one lot #85331 and level three lot #85333 were in use - The laboratory was using ranges wider than the package insert guideline ranges as follows: (i) Level One - The package insert guideline range was 0.65-0.855 (aa) From 09/01/2023 through 09/30/2023, the laboratory was using a range of 0.48-0.96; (bb) From 10/01/2023 through 11/30/2023, the laboratory was using a range of 0.52-1.0. (ii) Level Three - The package insert guideline range was 26.1-36.9 (aa) From 09/01/2023 through 11/30/2023, the laboratory was using a range of 20.85-40.85. (4) The records were reviewed with the laboratory manager who stated on 01/03/2024 at 01:35 pm, the laboratory had used ranges wider than the package insert 3 SD (standard deviation) guideline ranges as shown above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of two persons. Findings include: (1) A review of personnel records for two persons performing moderate complexity testing from September 2022 through the current date identified the following: (a) Although an annual competency had been documented as completed on 06/02/2023, the competency form had not been signed and dated by the evaluator to definitively determine who performed the assessment. (2) The record was reviewed with the laboratory manager who stated on 01/03/2024 at 10:50 am, the competency assessment documentation had not been signed and dated by the evaluator.