Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1103235	11/13/2025
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 11/12/2025 through 11/13/2025. The laboratory was found in compliance with standard-level deficiencies cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with testing person #1, the laboratory failed to ensure three of three bottle of Clia Waived MultiTox Urine quality controls were stored as required by the manufacturer. Findings include: (1) On 11/12 /2025 and 10:30 am, observation of the laboratory freezer and interview with testing person #1, identified the following: (a) Three bottles of Clia Waived MultiTox Urine QC, lot # CC02667, storage temperature of -10 to -20 degrees Celsius. (2) A review of records from August 2025, showed the temperature colder than negative 20 degrees Celsius for 18 of 20 days of testing. (3) Interview with testing person #1 on 11/12 /2025 at 10:30 am confirmed the bottles were being stored below the manufacturer's stated temperature requirements.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory director failed to sign proficiency testing attestation statements for four of 15 events reviewed in 2024 and 2025. Findings include: (1) On 11/12/2025, a review of 2024 and 2025 chemistry and hematology proficiency testing events identified the following for four of 15 events: (a) First 2024 Chemistry Event - The attestation statement had not been signed by the laboratory director; (b) First 2024 Hematology Event - The attestation statement had not been signed by the laboratory director; (c) Third 2024 Hematology Event - The attestation statement had not been signed by the laboratory director; (d) First 2025 Chemistry Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with testing person #1, who stated on 11/12/2025 at 10:00 am, the attestation statements had not been signed by the laboratory director.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with testing person #1, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 11/12/2025 at 10:10 am, identified the following expired supplies were available for use: (a) Four Greiner PST Gel and Lithium Heparin tubes, Lot 456087P, Exp. 08/31/2025 (b) 17 BD Vacutainer SST tubes, Lot 4305369 Exp. 10/31 /2025 (c) Five UTM-RT Specimen collection swabs, Lot 220219, Exp. 04/19/2025 (d) One Gallon Citranox solution, Lot 015099590223571, Exp. 01/31/2025 (2) Interview with testing person #1 on 11/12/2025 at 10:30 am confirmed the expired supplies were available for use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to utilize the demonstrated reportable ranges for five of five analytes reviewed for the Ortho Vitros XT 3400 test system. Findings include: (1) On 11/13/2024 at 10:

	00 am, testing person #1 stated the laboratory began using the Ortho Vitros XT 3400 analyzer to perform routine chemistry testing which included the analytes ALKP (Alkaline Phosphatase), GLU (Glucose), UREA (Urea Nitrogen), TRIG (Triglycerides), and TBIL (Total Bilirubin) in January 2024; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable ranges for five of five analytes reviewed: (a) ALKP - 25-1372 (b) GLU - 34.6-598.8 (c) TBIL - 1.08-18.39 (d) TRIG - 28.3-454.3 (e) Urea - 3.2-114.3 (3) Interview with testing person #1 on 11/13/2025 at 10:00 am confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) ALKP - 20-1500 (b) GLU - 20-625 (c) TBIL - 0.1-30 (d) TRIG - 10-525 (e) Urea - 2-120
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following: This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to ensure system checks were within the manufacturer's acceptable limits for 16 of 23 weeks reviewed. Findings include: (1) On 11/12/2025 at 12:50 pm, testting person #1 stated the laboratory performed Vitamin D, Thyroid Stimulating Hormone, Sex Hormone Binding Globulin, Testosterone, and Free T4 testing using the Beckman Access 2 test system: (2) A review of the Access 2 instructions for use stated, "Perform weekly system check, if results are not acceptable, Rerun, Troubleshoot System Check Results, or contact Technical Support"; (3) A review of the maintenance logs from June 2025 through November 2025 identified the following weekly system check failures: (a) 06/13/2025 to 09/26/2025 - the weekly system checks failed; (4) On 11/12/2025 at 12:50 pm, testing person #1 confirmed that the laboratory failed to ensure the weekly system checks were within manufacturer's acceptable limits.