Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1103235	10/30/2019
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 10/30/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, testing person #1, and testing person #2 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 testing person #1, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2018 and to date in 2019. There was no evidence competencies had been performed for technical consultant #2 based on their job responsibilities; (2) The surveyor asked testing person #1 if a written policy to evaluate the technical consultant based on job responsibilities was available and if competencies had been performed during the review period. Testing person #1 stated a policy to evaluate the technical consultant based on job responsibilities had not been written; and competencies had not been performed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results

	within the laboratory's stated performance specifications for each test system as determined under 493.1253. 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 follow the manufacturer's instructions for verifying flagged results. Findings include: (1) At the beginning of the survey, testing person #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (b) Manual differential testing was not performed in house. If a manual differential was required, the specimen would be sent to a reference laboratory. (2) Later during the survey, the surveyor reviewed the manufacturer's instructions for verifying flags obtained on the analyzer. For AG flags, the instructions stated, "Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc". In addition, the instructions stated, "Check Smear. etc"; (3) The surveyor randomly reviewed 4 patient records which contained AG flags from CBC testing performed between April 2019 through the day of the survey. For 4 of 4 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the AG flags. The findings for the 4 records were: (a) Patient testing was performed on 04/15/19, with an AG flag obtained next to Platelet; (b) Patient testing was performed on 05/10/19, with an AG flag obtained next to Platelet; (c) Patient testing was performed on 07/30/19, with an AG flag obtained next to Platelet; (d) Patient testing was performed on 10/15/19, with an AG flag obtained next to Platelet. (4) The surveyor reviewed the records with testing person #1, who stated the flags obtained for the above 4 patients had not been verified as required by the manufacturer.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports and interview with testing person #1, the laboratory failed to ensure patient test reports included either the patient's name and identification number, or a unique patient identifier and identification number. Findings include: (1) During the survey, the surveyor reviewed 3 patient reports from testing performed in the laboratory. The reports did not include a second unique identifier (only the patient's first and last name and date of birth were on the reports). The reports were: (a) #1 - KOH prep testing performed on 10/10/19 (b) #2 - Wet prep testing performed on 10/25/19 (c) #3 - CMP, Lipid Panel, Uric Acid, Urine Microscopic, CK (Creatine Kinase), TSH (Thyroid Stimulating Hormone), Free T4 (Thyroxine), Vitamin D, and CBC (Complete Blood Count) testing performed on 10 /25/19 (2) The surveyor reviewed the reports with testing person #1 who stated they

	did not include a second unique identifier. CMP (Comprehensive Metabolic Panel) - BUN, Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, Sodium, Albumin, ALT, AST, Alkaline Phosphatase, Total Bilirubin, and Total Protein Lipid Panel - Cholesterol, HDL Cholesterol, Triglyceride