Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469542	07/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kelley Family Clinic	13190 Ne 23rd St, Choctaw, 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 07/20/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, office manager, and testing person #1 at the conclusion of the survey.
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 office manger, the laboratory failed to ensure attestation statements were signed by the analyst(s) for 1 of 5 events. Findings include: (1) The surveyor reviewed 2019 (third event), 2020 (first, second, and third events) and 2021 (first event) Hematology proficiency testing records, with the following identified: (a) Second 2020 Event - The attestation statement had not been signed by the analyst(s). (2) The surveyor reviewed the records with the office manager who stated on 07/20/2021 at 11:30 am, the attestation statement had not been signed by the analyst(s), as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(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 a review of records and interview with the office manager, the laboratory failed to ensure control materials were not used beyond the expiration date for 3 of 12 lot numbers. Findings include: (1) On 07/20/2021 at 09:30 am, the office manager stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (b) Three levels of Sysmex Eight Check 3WP quality control (QC) materials were performed each day of patient testing. (2) The surveyor reviewed QC records for 12 lot numbers of QC materials used from 09 /24/2020 through the day of the survey. It was identified controls had been used beyond the manufacturer's expiration date for 3 of 12 lot numbers reviewed as follows: (a) Low control lot #10550710, normal control lot #10550711, and high control lot # 10550712 used from 03/15/2021 through 06/04/2021. The manufacturer's expiration date was 06/02/2021. (3) The records showed a patient CBC had been reported on 06/03/2021 at 08:33 am when the laboratory had used expired QC materials to assess the acceptable performance of the analyzer; (4) The surveyor reviewed the records with the office manager and laboratory director. Both stated on 07/20/2021 at 12:15 pm, the controls had been used beyond the expiration date.