Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475217	09/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Okmulgee Pediatrics & Family Care	916 E 8th St, Okmulgee, 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	A recertification survey was performed on 09/16/19. The findings were reviewed with the laboratory director, technical consultant, and testing person #1 during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to test proficiency testing samples the same number of times that patient samples were tested. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed Hemogram testing using the Horiba Micros 60 analyzer; (2) Later during the survey, the surveyor reviewed Hematology proficiency testing records for 5 events (First 2018, Second 2018, Third 2018, First 2019, and Second 2019 Events) and identified the specimens had been tested multiple times for 4 of 5 events as follows: (a) First 2018 Event (i) Sample HEM-03 was tested two times (03/20/18 at 10:02 a.m. and 03/20/18 at 10:08 a. m.) with the results obtained from the first run reported to the proficiency testing program. (b) Third 2018 Event (i) Sample HEM-11 was tested two times (11/26/18 at 01:31 p.m. and 11/26/18 at 01:50 p.m.) with the results obtained from the first run reported to the proficiency testing program; (ii) Sample HEM-13 was tested two times (11/26/18 at 01:41 p.m. and 11/26/18 at 01:56 p.m.) with the results obtained from the first run reported to the proficiency testing program. (c) First 2019 Event (i) Sample HEM-02 was tested two times (03/15/19 at 08:44 a.m. and 03/15/19 at 09:00 a.m.) with the results obtained from the first run reported to the proficiency testing program.

	(d) Second 2019 Event (i) Sample HEM-08 was tested two times (07/11/19 at 11:39 a. m. and 07/11/19 at 11:55 a.m.) with the results obtained from the first run reported to the proficiency testing program. (3) The surveyor reviewed the records with the technical consultant and asked if patient samples were tested in the same manner. The technical consultant stated patient specimens were routinely tested one time and not in duplicate as the proficiency testing specimens had been tested.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to perform at least two levels of control testing at least once a day patient specimens were tested. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor: (a) The laboratory performed Hemogram testing using the Horiba ABX Micros 60 hematology analyzer; (b) Three levels (low, normal and high) of Horiba quality control (QC) materials were to be tested each day of patient testing. (2) Later during the survey, the surveyor reviewed QC and patient records for testing performed between January 2019 through March 2019. It was identified QC testing had not been performed each day of patient testing for 1 of 63 days: (a) Patient Testing performed on 02/26/19. (3) The surveyor reviewed the records with the technical consultant. The technical consultant stated QC testing had not been performed each day of patient testing.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the manufacture's instructions and interview with the technical consultant, the laboratory failed to follow the manufacturer's specifications for quality control materials. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor: (a) Hemogram testing was performed on the Horiba ABX Mircros 60 hematology analyzer; (b) The laboratory tested 3 levels (Low, Normal, High) of Horiba Minotrol Quality Control (QC) materials each day of patient testing. (2) Later during the survey, the surveyor reviewed the manufacturer's instructions titled, "Quality Control Guidelines" which stated, (a) "The published assay means and ranges of a commerical hematology control (Diffitrol, Minotrol 18 or others) are considered a ranges of means." (3) The surveyor then reviewed QC records for testing performed from May 2019 through the day of the survey (09/16/19). It was identified the laboratory had used the package insert ranges, instead of laboratory

	established ranges, to determine acceptability of QC results for 3 of 12 lot numbers: (a) Low, Normal, and High control lot MX419 used from 09/04/19 through 09/16/19. (4) The surveyor reviewed the findings with the technical consultant who stated the laboratory had used the package insert ranges instead of laboratory established ranges for determining acceptability of QC results.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be

	qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) At the beginning of the survey, the surveyor reviewed records for 6 persons performing moderate complexity testing in 2018 and 2019. The records indicated the evaluations for 3 of 6 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 (i) The 2018 evaluation had been performed by the testing person #2 on 02 /20/18 (this person had earned a high school diploma); (ii) The 2019 evaluation had been performed by the testing person #2 on 02/20/19. (b) Testing Person #4 (i) The 2018 evaluation had been performed by the testing person #2 on 01/08/18; (ii) The 2019 evaluation had been performed by the testing person #2 on 01/09/19. (c) Testing Person #5 (i) The 2018 evaluation had been performed by the testing person #2 on 09 /19/18; (ii) The 2019 evaluation had been performed by the testing person #2 on 09/05 /19. (2) The surveyor explained to the technical consultant that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).