Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475217	10/13/2021
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	The recertification survey was performed on 10/13/2021. The findings were reviewed with testing person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 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 a review of records and interview with testing person #1, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for 5 of 5 patient specimens. Findings include: (1) On 10/13/2021 at 10:30 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument: (i) BD Veritor System - qualitative detection of SARS-CoV-2 nucleocapsid antigens from direct nasal swabs. (2) The surveyor reviewed the manufacturer's product insert titled, "BD Veritor System". Under the section titled, "Specimen Transport and Storage" which stated, "Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. It is essential that correct specimen collection and preparation methods be followed."; (3) The surveyor reviewed 5 test reports for patients tested on 04/07/2021 and 10/12/2021 and identified the following: (a) Patient Report #1 - Although the specimen collection date and time (04/07/2021 at 09:42 am) was documented, the result date and time was not on the patient report; (b) Patient Report #2 - Although the specimen collection date and time (04/07/2021 at 11:50 am) was documented, the result date and time was not on the patient report; (c) Patient Report #3 - Although the specimen collection date and time (10/12/2021 at 10:41 am)

	was documented, the result date and time was not on the patient report; (d) Patient Report #4 - Although the specimen collection date and time (10/12/2020 at 11:04 am) was documented, the result date and time was not on the patient report; (e) Patient Report #5 - Although the specimen collection date and time (10/12/2021 at 03:19 pm) was documented, the result date and time was not on the patient report. (4) The surveyor was not able to determine if the results had been interpreted within 1 hour after inoculation since the specimen collection date and time was not on the patient report; (5) The surveyor reviewed the records with testing person #1. Testing person #1 stated on 10/13/2021 at 02:00 pm the laboratory could not prove the results had been interpreted within 1 hour after inoculation as indicated above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to review and evaluate proficiency testing results for 1 of 5 events. Findings include: (1) On 10/13/2021, the surveyor reviewed 2020 and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2020 Hematology Event (i) MCH (Mean Corpuscular Hemoglobin) - 3 of 5 results exhibited a positive bias (aa) Sample HEM-01 - SDI of 2.0 (bb) Sample HEM-03 - SDI of 2.3 (cc) Sample HEM-05 - SDI of 3.2 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with testing person #1. Testing person #1 stated on 10/13/2021 at 01:10 pm the biases had not been addressed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 demonstrate the reportable ranges for a relocated analyzer. Findings include: (1) On 10/13/2021 at 10:30 am, testing person #1 stated to the surveyor the laboratory relocated the Horiba ABX Micros 60 analyzer to a new location on 08/25/2020 to perform CBC (Complete Blood Count) testing; (2) The surveyor reviewed the performance specification records for the analyzer and identified the laboratory had not demonstrated the reportable ranges for each analyte: (3) The surveyor reviewed the findings with testing person #1 who stated on 10/13/2021 at 02:35 pm the reportable ranges had not been verified.

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 testing person #1, 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 testing person #1, the laboratory

	failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 4 competency evaluations performed. Findings include: (1) On 10/13/21, the surveyor reviewed records for 4 persons performing moderate complexity testing in 2020 and to date in 2021 (10/13 /2021). The records showed the evaluations for 3 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 02/24/2020 and 02/25/2021 evaluations had been performed by testing person #1 (this person had earned a high school diploma); (b) Testing Person #3 - The 08/27/2020 ad 08/20/2021 evaluations had been performed by testing person #1; (c) Testing Person #4 - The 08/31/2021 evaluation had been performed by testing person #1. (2) The surveyor reviewed the records with testing person #1 and explained 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). Testing person #1 stated to the surveyor on 10/13/2021 at 10:50 am, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.