Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0965880	06/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Muskogee Pediatrics & Family Health Solutions	3505 W Broadway, Muskogee, 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 laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the office manager and testing person #1 at the conclusion of the survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the office manager and testing person #1, the laboratory failed to follow its written policy and procedure for the testing performed. Findings include: (1) At the beginning of the survey, the office manager and testing person #1 stated to the surveyor the laboratory used the Medonic M-Series analyzer to perform patient CBC testing (Complete Blood Count) (e.g., WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, and MCHC-Mean Corpuscular Hemoglobin Concentration, etc.); (2) In addition, the office manager and testing person #1 stated to the surveyor the laboratory analyzed 3 levels (1,2, and 3) of CDS Boule Con-Diff QC (Quality Control) materials each day of patient testing. The office manager and testing person #1 also stated patient test results could only be reported if the results of the 3 levels of QC were within the acceptable limits; (3) The surveyor reviewed the laboratory's QC policy and procedure for hematology testing, which stated that, "Our policy is that all 3 controls have to pass before testing patient samples."; (4) The surveyor then reviewed records from 7 months (January, April, August, and December 2017; January, April, and May 2018) for the 21 QC lot numbers used during the review period. From the records, the surveyor identified on 04/27/18 the results of 1 of the 3

	QC lot numbers (Level 1, lot #2180221, in use January 2017-April 2017) were unacceptable, as follows: (a) 09:53 AM - Level 1 was analyzed. The WBC, RBC, and Hemoglobin results were unacceptable; (b) 09:55 AM - Level 1 was repeated and the WBC result remained unacceptable. The corrective action documented was "Prime cycle;" (c) 09:59 AM - Level 1 was repeated. The WBC result remained unacceptable; (d) 10:03 AM - Level 1 was repeated. The RBC result was unacceptable and the WBC result was acceptable; (e) 10:04 AM - Level 1 was repeated. The RBC result was acceptable and the WBC was unacceptable. The corrective action documented was "Clean orifice;" (f) 10:06 AM - Level 1 was repeated. The WBC result remained unacceptable; (g) 10:09 AM - Level 1 was repeated. The WBC result remained unacceptable. No additional QC testing was performed and no further corrective action was documented; (h) Four patient CBC's were reported when the QC Level 1 WBC result was unacceptable (Patient 12, tested at 10:52 AM; patient #13, tested at 11:30 AM; patient #14, tested at 11:51 AM; and patient #15, tested at 03:57 PM). (5) The surveyor reviewed the findings with the office manager and testing person #1 who stated to the surveyor the laboratory did not follow its QC policy and procedure to report patient results only when the results of all 3 levels of QC materials were within the acceptable limits.
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 the office manager and testing person #1, the laboratory failed to follow the manufacturer's instructions. Findings include: (1) At the beginning of the survey, the office manager and testing person #1 stated to the surveyor the laboratory performed urine and throat cultures. In addition, the following was explained: (a) Urine: (i) Patient urine was streaked onto a Healthlink TSA (Trypticase Soy Agar) with 5% Sheep Blood culture media plate; (ii) The plate was incubated at 35-37 degrees C (Centigrade) overnight; (iii) The plate was examined the next morning; (iv) The result was reported as "Negative" if there was no bacterial growth seen on the plate, or "Positive" if bacterial growth was present. (b) Throat: (i) The patient throat swab was inoculated and streaked on a Healthlink SSA (Strep Select Agar) culture media plate; (ii) The plate was incubated at 35-37 degrees C overnight; (iii) The plate was examined the next day; (iv) The result was reported as "Negative" if no beta-hemolysis was observed on the SSA plate or reported "Positive" if beta-hemolysis was observed on the SSA plate. (2) The surveyor then reviewed the manufacturer's instructions (package insert) for the agar plates and identified the following information: (a) TSA: (i) "Incubate plates media side up at 33-37 degrees C for 18-24 hours;" (ii) "Limitations" - The ability to detect microorganisms by culture techniques can be affected by improper length of culture incubation. (b) SSA: (i) Procedure: "Incubate the plates in ambient air (or in an atmosphere enriched with 50 to 10% CO2) at 33-37 degrees C for 18-48 hours. Note: Pathogens may be detected as early as 18 hours however it is recommended that inoculated plates be incubated for a total of 48 hours before reporting a culture as "normal flora;" (ii) Results: "Growth should be evident after 18-48 hours of incubation. Beta hemolytic Streptococci may be

	presumptively identified as small, translucent to opaque colonies surrounded by zones of beta hemolysis;" (iii) Limitations: "The ability to detect microorganisms by culture techniques can be affected by the following factors: improper collection, storage and inoculation, initiation of antiinfective therapy prior to specimen collection, improper culture incubation temperatures and atmospheres, improper length of culture incubation, and improper storage and handling of culture media." (3) The surveyor then reviewed the patient culture log book for testing performed from 10/01/16 through the day of the survey. The surveyor identified patient cultures which had not been interpreted after the appropriate incubation period as required by the manufacturer's instructions: (a) Urine Cultures - The following cultures were incubated for less than 18 hours (minimum incubation period required by manufacturer) before being resulted: (i) Patient #1: Final result - "Negative" (i.e. no bacterial growth observed) (aa) Inoculation: 10/05/16 at 03:25 PM (bb) Interpretation: 10/06/16 at 07:45 AM (cc) Incubation time: 16 hours, 20 minutes (ii) Patient #2: Final result - "Negative" (aa) Inoculation: 02/01/17 at 06:10 PM (bb) Interpretation: 02/02 /17 at 07:45 AM (cc) Incubation time: 13 hours, 35 minutes (iii) Patient #3: Final result - "Negative" (aa) Inoculation: 09/11/17 at 04:20 PM (bb) Interpretation: 09/12 /17 at 08:00 AM (cc) Incubation time: 15 hours, 40 minutes (v) Patient #4: Final result - "Negative" (aa) Inoculation: 02/05/18 at 02:38 PM (bb) Interpretation: 02/06/18 at 08:01 AM (cc) Incubation time: 17 hours, 23 minutes (vi) Patient #5: Final result - "Negative" (aa) Inoculation: 04/13/18 at 03:55 PM (bb) Interpretation: 04/14/18 at 08: 00 AM (cc) Incubation time: 16 hours, 5 minutes (b) Throat cultures - The following cultures were incubated for less than 48 hours (minimum incubation period required by manufacturer) before being resulted as normal flora: (i) Patient #6: Final result - "Negative" (i.e., no beta-hemolyis observed) (aa) Inoculation: 12/22/16 at 05:46 PM (bb) Interpretation: 12/23/16 at 07:45 AM (cc) Incubation time: 12 hours, 59 minutes (ii) Patient #7: Final result - "Negative" (aa) Inoculation: 09/11/17 at 02:40 PM (bb) Interpretation: 09/12/17 at 08:00 AM (cc) Incubation time: 17 hours, 20 minutes (iii) Patient #8: Final result - "Negative" (aa) Inoculation: 11/20/17 at 10:05 AM (bb) Interpretation: 11/21/17 at 07:55 AM (cc) Incubation time: 21 hours, 50 minutes (iv) Patient #9: Final result - "Negative" (aa) Inoculation: 02/07/18 at 09:30 AM (bb) Interpretation: 02/08/18 at 08:10 AM (cc) Incubation time: 22 hours, 30 minutes (4) The surveyor reviewed the findings with the office manager and testing person #1. The office manager and testing person #1 stated to the surveyor the cultures listed above, had not been incubated for the minimum time required by the manufacturer of the culture media to ensure accurate results.