

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0965880	(X3) Date Survey Completed 11/12/2020
Name of Provider or Supplier Muskogee Pediatrics & Family Health Solutions	Street Address, City, State 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 recertification survey was performed on 11/12/2020. The findings were reviewed with laboratory owner/testing person #1, testing person #2, and testing person #3 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory owner /testing person #1 and testing person #3, the laboratory failed to have a written employee competency policy that explained each component of a required competency for moderate complexity testing. Findings include: (1) On 11/12/2020, the surveyor reviewed the Laboratory Procedure Manual. The section that specified training and competency of testing personnel did not include the following components: (a) Direct observations of routine patient test performance, including patient preparation, specimen handling, processing and testing, required at 493.1413(b)(8)(i) - D6047; (b) Monitoring the recording and reporting of test results, required at 493.1413(b)(8)(ii) - D6048; (c) Review of test results or worksheets, quality control records, and proficiency testing records, required at 493.1413(b)(8)(iii) - D6049; (d) Direct observation of performance of instrument maintenance and function checks, required at 493.1413(b)(8)(iv) - D6050; (e) Assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples, required at 493.1413(b)(8)(v) - D6051; (f) Assessment of problem solving skills, required at 493.1413(b)(8)(vi) - D6052. (2) The surveyor asked the laboratory owner/testing person #1 and testing person #3 to explain what was included</p>

in the evaluations. The laboratory owner/testing person #1 and testing person both stated on 11/20/2020 at 03:00 pm the laboratory did not have a competency assessment policy as indicated above.

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 the policy and procedure manual and interview with the laboratory owner/testing person #1 and testing person #3, the laboratory failed to follow written procedures for CBC (Complete Blood Test) testing performed. Findings include: (1) On 11/12/2020 at 10:00 am, the laboratory owner/testing person #1 and testing person #3 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M-Series analyzer; (2) The surveyor reviewed written laboratory procedure titled, "*Policy and Procedure for Medonic Maintenance*" which stated, (a) "9. Opening new lot # for the controls must be run 5 days prior to using them with the current lot number that is already being used. That is to be done only once in the morning together to ensure they are of good quality." (3) The surveyor reviewed 15 QC (quality control) lot numbers. For 6 of 15 lot numbers there was no indication the laboratory staff followed their written procedure as follows: (a) Lot# 2200601 ran 2 times before put into use on 08/07/2020 (b) Lot# 2200602 ran 2 times before put into use on 08/07/2020 (c) Lot# 2200603 ran 2 times before put into use on 08/07/2020 (d) Lot# 2200821 ran 2 times before put into use on 09/17/2020 (e) Lot# 2200822 ran 2 times before put into use on 09/17/2020 (f) Lot# 2200823 ran 2 times before put into use on 09/17/2020 (4) The surveyor reviewed the findings with the laboratory owner/testing person #1 and testing person #3. Both stated on 11/12/2020 at 03:10 pm that the procedure had not been followed as indicated above.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory owner/testing person #1 and testing person #3, the laboratory director failed to ensure personnel had the appropriate training for performing moderate complexity testing. Findings include: (1) On 11/12/2020, the surveyor reviewed personnel records for 3 persons who had been hired to perform moderate complexity testing. There was no documented training for

2 of the 3 persons as follows: (a) Testing Person #1- 05/01/2020 (b) Testing Person #2 - 05/01/2020 (2) The surveyor reviewed the records with the laboratory owner/testing person #1 and testing person #3. Both stated on 11/12/2020 at 03:05 pm there was no documentation to prove the above persons had been trained. Moderate complexity test systems performed in the laboratory: 1. Medonic M-Series- CBC (Complete Blood Count)