

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473884	(X3) Date Survey Completed 05/30/2019
Name of Provider or Supplier Utica Park Clinic-Family Medical	Street Address, City, State 3316 E 21st, Suite A, Tulsa, 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 05/30/19. The laboratory was found out of compliance with the following CLIA regulation: 493.1421: D6033: Testing Personnel, Moderate Complexity The findings were reviewed with the laboratory director at the conclusion of the survey.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure proficiency testing samples were tested by personnel who routinely performed patient testing. Findings include: PART-TIME TESTING PERSON (1) At the beginning of the survey, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed prior to the survey. The form listed 4 testing persons (Testing person #1, testing person #2, testing person #3, and testing person #4) as performing the moderate complexity testing in the laboratory; (2) The laboratory director stated to the surveyor the moderate complexity laboratory testing performed was CBC (Complete Blood Count) (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing using the Medonic CA620 hematology analyzer; (3) The surveyor then reviewed Hematology proficiency testing records for the Third 2017 Event; the First, Second and Third 2018 Events; and the First 2019 Event and identified testing person #4 had not performed proficiency testing in 5 of the 5 Hematology proficiency testing events; (4) The surveyor asked the laboratory director if testing person #4 had been trained to perform CBC testing. The laboratory director stated to the surveyor, testing person #4 had been trained and would fill in and perform patient testing if the laboratory was short-</p>

staffed; (5) The surveyor reviewed the findings with the laboratory director, who stated to the surveyor the laboratory failed to ensure proficiency testing had been performed by all testing persons who performed patient testing. FLOAT TESTING PERSON (1) The surveyor reviewed patient test records (i.e. Specimen Log Sheets) from October 2017 through March 2019 and identified initials of an individual who performed patient testing, but who had not been listed on the Laboratory Personnel Form (Testing person #5); (2) The surveyor reviewed proficiency testing records again but could not locate documentation that proved testing person #5 had analyzed proficiency testing samples in 5 of the 5 events; (3) The surveyor asked the laboratory director if testing person #5 performed patient CBC testing. The laboratory director stated to the surveyor, testing person #5 was a float testing person who would fill in whenever the laboratory was short-staffed; (4) The surveyor reviewed the findings with the laboratory director who stated to the surveyor the laboratory failed to ensure proficiency testing had been performed by all testing persons who performed patient testing.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory director, the laboratory failed to take corrective actions for unacceptable proficiency testing results. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the moderate complexity testing performed by the laboratory was CBC (Complete Blood Count) (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing using the Medonic CA620 hematology analyzer; (2) The surveyor reviewed Hematology proficiency testing records for the Third 2017 Event; the First, Second and Third 2018 Events; and the First 2019 Event. The surveyor identified the laboratory obtained 80% scores for automated WBC differentials in the First 2019 Event, as follows: (a) Granulocytes %: 1 of the laboratory's 5 responses was unacceptable: (i) Sample HEM-04: (aa) The laboratory reported, "12.3%;" (bb) The proficiency testing program's expected response was, "53.7-62.1%;" (cc) There was no documentation corrective action (i.e. repeat sample, review controls, calibration, maintenance, etc.) had been taken for the unacceptable response. (b) Lymphocytes %: 1 of the laboratory's 5 responses was unacceptable: (i) Sample HEM-04: (aa) The laboratory's response was, "7.2%;" (bb) The proficiency testing program's expected response was, "30.3-37.0%;" (cc) There was no documentation corrective action had been taken for the unacceptable response. (c) Monocytes/Mids %: 1 of the laboratory's 5 responses was unacceptable: (i) Sample HEM-04: (aa) The laboratory's response was, "1.9%;" (bb) The proficiency testing program's expected response was, "6.1-10.8%;" (cc) There was no documentation corrective action had been taken for the unacceptable response. (3) The surveyor reviewed the findings with the laboratory director who stated to the surveyor, the laboratory failed to take corrective action for the unacceptable proficiency testing responses listed above.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 laboratory director, the laboratory failed to verify the stated value of control materials before use. Findings include: (1) At the beginning of the survey, the laboratory director stated the following to the surveyor: (a) The laboratory used the Medonic CA620 hematology analyzer to perform CBC (Complete Blood Count) (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing; (b) Three levels (Low, Normal, and High) of CDS Boule Con-Diff QC (Quality Control) materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of the QC results. (2) The surveyor reviewed records for 21 QC lot numbers. For 3 of the 21 QC lot numbers reviewed, there was no documentation the laboratory verified the provided ranges before the lot numbers were put into use: (a) Low control, Lot #2171151-In use from 12/31/17-03/15/18 (b) Normal control, Lot #2171152-In use from 12/31/17-03/15/18 (c) High control, Lot #2171153-In use from 12/31/17-03/15/18 (3) The findings were reviewed with the laboratory director who stated to the surveyor, the manufacturer's ranges for the QC lot numbers listed above, had not been verified prior to being put into use. NOTE: D5469 was cited at the previous recertification survey performed 08/03/17.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure all proficiency testing reports were reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Findings include: (1) The laboratory director failed to ensure corrective actions were taken for unacceptable proficiency testing results. Refer to D5221.

D6063

LABORATORY TESTING PERSONNEL
 CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to ensure individuals who performed moderate complexity testing met the educational qualification requirements as listed in 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of testing performed. Findings include: (1) The laboratory failed to ensure a testing person met the educational qualifications. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to ensure a testing person met the required educational qualifications to perform moderate complexity testing. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the only moderate complexity testing performed by the laboratory was CBC (Complete Blood Count) testing performed on the Medonic CA620 hematology analyzer; (2) The surveyor reviewed the Laboratory Personnel Report (CMS Form-209) completed by the laboratory prior to the survey. The form listed 4 testing persons who performed the moderate complexity laboratory testing (Testing person #1, testing person #2, testing person #3, and testing person #4); (3) During the survey, the surveyor reviewed testing records (i.e. Specimen Log Sheets) and identified an individual (testing person #5) not listed on the CMS Form-209 had performed patient CBC testing. The surveyor asked the laboratory director if testing person #5 performed patient CBC testing. The laboratory director stated to the surveyor, testing person #5 was a float testing person who would fill in whenever the laboratory was short-staffed; (4) The surveyor then reviewed the personnel records again but could not find education documents (a minimum of a high school diploma /transcript or equivalent - GED) for the individual; (5) The surveyor asked the laboratory director if educational documents were available for testing person #5. The laboratory director stated to the surveyor there were no educational documents available for testing person #5.

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to document the initial training of a testing person prior to performing patient testing Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the moderate complexity laboratory testing performed was CBC (Complete Blood Count) (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) testing using the Medonic CA620 hematology analyzer (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed by the laboratory prior to the survey. The form listed 4 testing persons (Testing person #1, testing person #2, testing person #3, and testing person #4) as performing the moderate complexity testing; (3) During the survey, the surveyor reviewed testing records (i.e. Specimen Log Sheets) and identified an individual (testing person #5) not listed on the CMS Form-209 had performed patient CBC testing. The surveyor asked the laboratory director if testing person #5 performed patient CBC testing. The laboratory director stated to the surveyor, testing person #5 was a float testing person who would fill in whenever the laboratory was short-staffed; (4) The surveyor reviewed the personnel records but could not locate documentation that testing person #6 had been initially trained to perform testing at the laboratory; (5) The surveyor asked the laboratory director if there was documentation which showed an initial training and competency evaluation had been performed for testing person #5. The laboratory director stated to the surveyor testing person #5 had been trained at another laboratory to perform the testing but there was no documentation of initial training and competency evaluation at this laboratory.