

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0670094	<b>(X3) Date Survey Completed</b>  01/30/2020
<b>Name of Provider or Supplier</b>  Utica Park Clinic - Broken Arrow South	<b>Street Address, City, State</b>  2617 S Elm Place, Broken Arrow, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed 01/30/2020. The findings were reviewed with the laboratory director at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1421: D6063: Condition: Testing Personnel, Moderate Complexity
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with the laboratory director, the laboratory failed to follow its written procedure for entering patient results. Findings include: MICROSCOPIC URINALYSIS (1) At the beginning of the survey, the laboratory director stated to the surveyor the laboratory performed microscopic examination of urine sedimentation; (2) The surveyor reviewed the laboratory's written policy and procedure, which included instructions for reporting patient results: (a) Observe 10 low power fields and average number of cellular components: (i) For Epithelial cells, Renal Epithelial cells, and Crystals, report the quantity seen/HPF (per High Power Field), as follows: (aa) Few (bb) Moderate (cc) Many (ii) If Bacteria is seen, quantitative and report as Rare, or 1+ to 4+/HP (3) The surveyor then reviewed reports of 9 microscopic patient urinalysis results and identified the laboratory failed to follow its written policy and procedure for 8 of the 9 microscopic urinalysis results reported. The findings follow: (a) Patient #889479, testing performed on 07/26/18: (i) Bacteria was not reported as "Rare, 1+, 2+, 3+, or 4+" but was reported as "TNTC." (b) Patient #605069, testing performed on 11/07/18: (i) Epithelial cells were not reported as "Few, Moderate, or Many" but were reported</p>

as "5-15;" (ii) Bacteria was not reported as "Rare, 1+, 2+, 3+, or 4+" but was reported as "TNTC;" (iii) Crystals were not reported as "Few, Moderate, or Many" but were reported as "0-3." (c) Patient #889479, testing performed 04/30/19: (i) Bacteria was not reported as "Rare, 1+, 2+, 3+, or 4+" but was reported as "TNTC." (d) Patient #0605069, testing performed on 09/03/19: (i) Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "0-5." (e) Patient #1765280, testing performed on 09/05/19: (i) Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "5-15;" (ii) Renal Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "2-4." (f) Patient #1535167, testing performed on 10/15/19: (i) Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "0-5;" (ii) Bacteria was not reported as "Few, Moderate, or Many" but was reported as "TNTC." (g) Patient #1504530, testing performed on 12/26/19: (i) Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "0-5;" (ii) Renal Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "2-4." (h) Patient #1524082, testing performed on 01/15/20: (i) Epithelial cells were not reported as "Few, Moderate, or Many" but were reported as "5-15;" (ii) Bacteria was not reported as "Few, Moderate, or Many" but was reported as "TNTC." (4) The surveyor reviewed the findings with the laboratory director. The laboratory director stated to the surveyor the laboratory failed to report results of microscopic urinalysis as the policy and procedure directed. VAGINAL WET PREP EXAMINATIONS (1) The surveyor reviewed the laboratory's written policy and procedure for vaginal wet prep examinations, which included instructions for reporting patient results: (a) For Clue Cells, report the number seen, as follows: (I) None (ii) Few (iii) Moderate (iv) Many (b) If Bacteria is seen, quantitate and report as Rare, or 1+ to 4+/HP (2) The surveyor then reviewed reports of 2 vaginal wet prep examinations and identified the laboratory failed to follow its written policy and procedure for 2 of 2 results reported. The findings follow: (a) Patient #1407134, testing performed on 01/15/19: (i) Bacteria was not reported as "Rare, 1+, 2+, 3+, or 4+" but was reported as "Positive." (b) Patient #1354091, testing performed on 08/08/19: (i) Bacteria was not reported as "Few, Moderate, or Many" but was reported as "+" (ii) Clue cells were not reported as "None, Few, Moderate, or Many" but were reported as "+" (3) The surveyor reviewed the findings with the laboratory director. The laboratory director stated to the surveyor the laboratory failed to report the results of vaginal wet prep examinations as the policy and procedure directed.

**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 an individual 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 for 1 of 1 previously employed individuals. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (WBC- White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Beckman Coulter AcT Diff 2 analyzer until 06/17/19 when CBC testing was stopped; (2) During the survey, the surveyor identified 1 previously employed individual not listed on the Form CMS-209, who had performed the moderate complexity testing: testing person #5 (between 01/29/19 and 06/14/19). The surveyor then reviewed the personnel records but could not find the educational documents (i.e. transcript, diploma, GED certificate) for the 1 previously employed testing person; (3) The surveyor asked the laboratory director if educational documents for testing person #5 were available for review. The laboratory director stated to the surveyor when testing person #5 terminated employment, testing person #5 removed their educational documents from the personnel records and there were no educational documents available for review. Therefore, the surveyor could not verify the previously employed testing person #5, met the educational qualifications for performing moderate complexity testing.