

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2026906	(X3) Date Survey Completed 05/04/2018
Name of Provider or Supplier Utica Park Clinic South Lewis	Street Address, City, State 7600 S Lewis, 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 findings were reviewed with the laboratory director/technical consultant at the conclusion of the survey.
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 policies and procedures, and interview with the laboratory director/technical consultant, the laboratory failed to have written policies and procedures for assessing employee competency. Findings include: (1) At the beginning of the survey, the surveyor reviewed the laboratory's policies and procedures. A policy that explained how employees were assessed for competency could not be located; (2) The surveyor asked the laboratory director/technical consultant if a competency policy was available for review. The laboratory director/technical consultant stated a policy had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records *Direct observation of performance of instrument maintenance and function checks *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples *Assessment of problem solving skills</p>

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 director/technical consultant, the laboratory failed to follow written procedures for CBC (Complete Blood Test) testing performed. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyor CBC (Complete Blood Count) was performed on the Beckman Coulter Act Diff 2 analyzer; (2) Later during the survey, the surveyor reviewed written procedure titled, "CBC REPEAT ANALYSIS" which stated, (a) "Anytime the CBC analyzer presents with any of the following flags: 1,2,4,M,X,*, or +. If the flags persist after rerun then the technician running the sample will take results to ordering doctor to see if they would like sample sent to reference lab." (3) The surveyor reviewed 3 patient records. For 3 of 3 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient #1 tested 02/21/17 at 9:59 - flagged "M" for Gran#, Gran%, Mono#, Mono (b) Patient #2 tested 05/05/17 at 11:00 am - flagged "3" for Gran#, Gran%, Mono#, Mono (c) Patient #3 tested 11/15/17 at 10:16 am - flagged "3" for Gran#, Gran%, Mono#, Mono (3) The surveyor reviewed the findings with the laboratory director/technical consultant who stated that the procedure had not been followed as indicated above.