

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0900629	(X3) Date Survey Completed 06/11/2019
Name of Provider or Supplier Advocate Medical Group Sykes	Street Address, City, State 2535 S Martin Luther King Drive, Chicago, IL	
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
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 the Laboratory Personnel Report (CMS 209), record review, and an interview with testing personnel (TP1); the laboratory failed to ensure proficiency test (PT) samples are tested by personnel who routinely perform the testing in the laboratory for 6 out of 6 PT events. Findings: 1. The laboratory's CMS 209, PT records and personnel files were reviewed. 2. TP1, TP2, TP3, and TP4 were authorized and assessed as competent to perform Cell Blood Count (CBC) analysis during the years of 2017, 2018 and 2019. 3. The PT attestation revealed that TP2, TP3, and TP4 failed to participate in the PT program during the years of 2017 through 2019. TP1 performed in 6 out of 6 PT events that occurred during those years. 4. On a Recertification survey conducted on 06/11/2019 at 12:30 PM, the laboratory director (LD) and TP1 confirmed the above findings.</p>
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review, manuals and an interview with testing personnel (TP1) and office staff; the laboratory failed to retain test reports for at least 2 years after the date of reporting for 1 out of 5 patients. Findings includes: 1. The procedures manual, test orders and results, and electronic medical records (EMR1 and EMR2) final reports were reviewed. 2. The procedure for testing patients for CBC analysis is as follows: *An order for CBC analysis is placed in EMR1 for patient XA1 *When patient XA1 arrives in the laboratory, the CBC order is retrieved from EMR1 and the patient is tested. *The results from patient XA1 is then faxed to the requesting physician. When the confirmation of receipt is received from the requesting physician, the laboratory then attaches the confirmation to the result sheet along with the test order sheet. *The laboratory is transitioning from EMR1 system to EMR2 system as of 2019. *Thus, at some future time, Patient XA1 completed order/result/confirmation packet will be manually entered into EMR2. 3. The review of 5 randomly selected patients' completed packets from 2019 and EMR2 final reports revealed the following *The EMR2 failed to retain the order, the test result and the date report for 1(Patient B5Y- tested 02/04/2019) out of 5 patients. *The laboratory failed to establish an ongoing mechanism to monitor, assess, and, when indicated, correct deletion errors that occur from the second EMR system. 4. On a Recertification survey conducted on 06/11 /2019 at 12:30 PM, the office staff and TP1 stated that there has been other patient data errors with the second EMR system and confirmed the above findings.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the testing personnel (TP1); the laboratory failed to establish written procedures that meet the requirement to assess employees performing Cell Blood Count (CBC) analysis, affecting 4 out of 4 TP. Findings include: 1. The procedures manual and personnel records were reviewed. 2. The laboratory failed to have a written competency procedure that includes the following requirements: *The assessment of problem solving skills. 3. On a Recertification survey conducted on 06/11/2019 at 12:30 PM, the laboratory director (LD) and TP1 confirmed the above findings.