

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0886124	(X3) Date Survey Completed 11/13/2019
Name of Provider or Supplier Advocate Infusion Center - Darien	Street Address, City, State 2622 83rd Street, Darien, 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 review of laboratory policies and procedures manuals, Laboratory Personnel Report - CLIA Form (CMS 209), proficiency testing records, and interview with testing person #1 and the practice manager; the samples were not tested by personnel who routinely perform the testing in the laboratory. Findings: 1. There were no written policies and procedures that described the laboratory's process for rotation of proficiency testing samples amongst all individuals who routinely perform hematology testing in the laboratory. 2. There are a total of 9 persons listed on the CMS 209 as moderate complexity testing personnel. 3. Review of proficiency testing records revealed that there were only 3 of 9 testing personnel who performed the proficiency testing for 3 proficiency testing events in 2018 and 3 proficiency testing events in 2019. 4. On November 14, 2019 at 11:00 AM, testing person #1 stated that she was responsible for performing proficiency testing. 5. On November 14, 2019 at 11:30 AM, the practice manager confirmed the surveyor's findings.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p>

This STANDARD is not met as evidenced by:
Based on review of Laboratory Personnel Report - CLIA Form (CMS 209) and proficiency testing records and interview with the practice manager, the individual testing or examining the samples and the laboratory director failed to attest to the routine integration of the samples into the patient workload. Findings: 1. Review of the CMS 209 revealed that the laboratory director listed himself as technical consultant. 2. Review of proficiency testing records revealed that the laboratory director failed to attest (sign and date the attestation statement) to the routine integration of the samples into the patient workload for proficiency testing events 1, 2, and 3 in 2018 and proficiency testing events 1, 2, and 3 in 2019. 3. On November 14, 2019 at 11:30 AM, the practice manager confirmed the surveyor's findings.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review of quality control records and interviews with testing person #1 and the practice manager, the laboratory failed to retain quality control records for at least 2 years as specified. Findings: 1. On November 14, 2019 at 11:00 AM, the surveyor reviewed 8 patients' test records along with their corresponding quality control records. 2. There were no manufacturers' assay information sheets for control materials available for review from January 2018 through September 2019. 3. On November 14, 2019 at 11:10 AM, testing personnel #1 stated that the laboratory only retains the manufacturer's information sheets for the labs current lot of quality control material. 4. On November 14, 2019 at 11:15 AM, the practice manager confirmed the surveyor's findings.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on review of Laboratory Personnel Report - CLIA Form (CMS 209), laboratory policies and procedures manuals, personnel records, and interview with the practice manager; the technical consultant failed to be responsible for assuring everyone performing tests receives training for hematology testing. Findings: 1. Review of the CMS 209 revealed that the laboratory director listed himself as technical consultant of the laboratory. 2. There are a total of 9 persons listed on the CMS 209 as testing personnel for moderate complexity hematology testing in the laboratory. 3. There are procedures that described the laboratory's process for training and documenting the training of testing personnel. 4. Review of personnel records for 9 testing personnel revealed that there was no documentation to show testing personnel were trained to perform hematology testing in the laboratory for 9 of 9 testing personnel for 2018 and

/or 2019. 5. On November 14, 2019 at 11:30 AM, the practice manager confirmed the surveyor's findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of Laboratory Personnel Report - CLIA Form (CMS 209), laboratory policies and procedures manuals, personnel records, and interview with the practice manager; the technical consultant failed to be responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of the CMS 209 revealed that the laboratory director listed himself as technical consultant of the laboratory. 2. There are a total of 9 persons listed on the CMS 209 as testing personnel for moderate complexity hematology testing in the laboratory. 3. There are procedures that described the laboratory's process for evaluating and documenting the performance of testing personnel responsible for moderate complexity hematology testing in the laboratory. 4. Review of 9 testing personnel records revealed that there was no documentation to show when everyone began testing in the laboratory for 9 of 9 testing personnel for 2018 and 2019. 5. There was no documentation to show the competency of testing personnel was evaluated at least semiannually in 2018 and 2019. 6. On November 14, 2019 at 11:30 AM, the practice manager confirmed the surveyor's findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of Laboratory Personnel Report - CLIA Form (CMS 209), laboratory policies and procedures manuals, personnel records, and interview with the practice manager; the technical consultant failed to be responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. Findings: 1. Review of the CMS 209 revealed that the laboratory director listed himself as technical consultant of the laboratory. 2. There are a total of 9 persons listed on the CMS 209 as testing personnel for moderate complexity hematology testing in the laboratory. 3. There are procedures that described the laboratory's process for evaluating and documenting the performance of testing personnel responsible for moderate complexity hematology testing in the laboratory. 4. Review of 9 testing personnel records revealed that there was no documentation to show when everyone began testing in the laboratory for 9 of 9 testing personnel for 2018 and 2019. 5. There was no documentation to show the

competency of testing personnel was evaluated in 2018 and 2019 for 9 of 9 testing personnel. 6. On November 14, 2019 at 11:30 AM, the practice manager confirmed the surveyor's findings.