

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0413340	(X3) Date Survey Completed 05/15/2018
Name of Provider or Supplier Coagulation Consultants Lab	Street Address, City, State 1640 Elk Blvd, Des Plaines, 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
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 the surveyor's review of the Laboratory Personnel Report (CMS 209), the laboratory's policies, procedures and records, and an interview with the technical supervisor (TS); the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Coagulation analysis, affecting 3 out of 3 testing personnel (TP). Findings: 1. The CMS 209 lists 3 TP performing Coagulation analysis in the laboratory. 2. The laboratory's manual and competency procedure does not include the following required competency evaluation processes: e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f). Assessment of problem solving skills. 3. On a Recertification survey conducted on May 15, 2018 at 11:15 AM, the TS confirmed the above findings.</p>
D6134	<p>CLINICAL CONSULTANT CFR(s): 493.1453</p> <p>The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the personnel records, and an interview with the technical supervisor (TS); the laboratory failed to have a clinical consultant (CC) who meets the qualification requirements. Findings: 1. The CC failed to be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care for testing in the Specialty of Hematology, during the year of 2018. See D6135.

D6135

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the personnel records, and an interview with the technical supervisor (TS); the laboratory failed to have a qualified Clinical Consultant (CC) for testing in the specialty of Hematology, affecting all patients tested during the year of 2018. Findings: 1. The CMS 209 lists employee "VT" on line 1 as the CC of the laboratory in which high complexity testing for Coagulation analysis is performed. 2. The employee files provided showed the following: a). Employee "VT" has a Doctor of Philosophy from an accredited university in the state of Illinois. b). Employee "VT" provided no documented evidence that he had been certified by a Health and Human Services (hhs) approved Board, when hired in January of 2018 as laboratory director (LD) and Clinical Consultant (CC). 3. On a Recertification survey conducted on 05/15/2018 at 2:00 PM, the TS confirmed the above findings and the LD stated that he will begin the board certification process.