

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0413340	(X3) Date Survey Completed 10/08/2020
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the technical supervisor (TS), the laboratory failed to enroll in an HHS approved proficiency testing (PT) program for the subspecialty of Hematology during the year of 2019. Findings include: 1. The laboratory's PT documents, quality control (QC) records, and Test Volume Worksheet were reviewed. 2. The final reports and QC records showed the following: *The laboratory was performing patient testing for the analytes: Prothrombin Time (PT), Fibrinogen, and Activated Partial Thrombin Time (aPTT). *The methods used to test for PT, Fibrinogen, and aPTT were non-waived. 3. The College of American Pathology (CAP) PT records showed the laboratory was enroll in the subspecialty of Coagulation testing during the years of 2018 and 2020; however the laboratory failed to re-enroll in 2019. 4. On 10/08/2020 at 10:30 AM, the TS confirmed the above findings and stated that the laboratory did not re-enroll in the CAP-PT program for the year of 2019.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the technical supervisor (TS), the laboratory failed to verify the accuracy of the Coagulation test and procedures it performs during the year of 2019. Findings include: The laboratory participates in the College of American Pathologists (CAP) PT program to verify the accuracy of its Coagulation tests and procedures. 1. The laboratory Test Volume Worksheet and the Hematology proficiency testing (PT) reports for 2018, 2019 and 2020 were reviewed. 2. The test volume worksheet revealed the following Coagulation tests and procedures performed in the laboratory: *Platelet Aggregation - Platelet Dense Granules (ADP); Collagen; Ristocetin, Epinephrine (EPI); Arachidonic Acid (Arach); Low Density Ratio (LDR); and Thrombin. *Activated Protein C Resistance *Anti Thrombin 3 Activity *Bethesda Titer *Circulating Anticoagulant (PT & APTT) *Lupus Like Anticoagulant (TTI & DRVVT) *Euglobulin Lysis Time *Heparin Platelet Aggregation *Heparin Platelet Antibody (HIT) *Factor V Leiden *Factor II, V, VII, VIII, IX, X, XI, XII, *Factor XIII *Methylenetetrahydrofolate reductase (MTHFR) 1298 *MTHFR C677T *Protein C Activity *Protein C Antigen *Protein S Activity *Protein S Antigen (Free, Total) *Prothrombin Gene Mutation *Factor VIII Related Antigen *Reptilase Time *Ristocetin Cofactor *Thrombin Time *Anti-Xa Activity 3. Review of the CAP-PT reports revealed proficiency testing were not performed in 2019 due to non- enrollment. 4. Further review showed that the laboratory failed to establish another method to verify the accuracy of its Coagulation tests and procedures when they did not re-enroll in the CAP-PT program. 5. On 10/08/2020 at 10:30 AM, the TS confirmed the above findings and stated that the laboratory did not re-enroll in the CAP-PT program for the year of 2019.