Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387943	06/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Cancer Specialists, Pc	1750 E 53rd Street, Davenport, IA	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1: 45 pm on 06/24/2021, the laboratory failed to take and document corrective action for three unacceptable PT scores from three out of six PT testing events (2019 event 2, 2020 event 1, and 2020 event 3) in 2019-2020. The findings include: 1. For 2019 testing event 2, the laboratory received unacceptable PT test scores for the following: *AAFP PT 2019-B: free thyroxine (FT4), specimen CH-9N 2. For 2020 testing event 1, the laboratory received unacceptable PT test scores for the following: *AAFP PT 2020-A: platelet count, specimen HD-5 3. For 2020 testing event 3, the laboratory received unacceptable PT test scores for the following: *AAFP PT 2020-C: platelet count, specimen HD- 15 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the unacceptable PT test scores.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:15 pm on 06/24/2021, the laboratory director failed to monitor individuals performing moderate complexity testing to ensure they are competent and maintain their competency for four out of four testing personnel (identifiers #2, #3, #10, and #11). The findings include: 1. Personnel identifiers #2, #3, #10, and #11 perform moderate complexity testing on both the Cell-Dyn Emerald hematology analyzer and the Frend System immunoassay analyzer. 2. Personnel competency assessments included only the Cell-Dyn Emerald hematology analyzer. 3. At the time of the survey, personnel identifier #2 confirmed that competency assessments did not include the Frend System immunoassay analyzer.