Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387943	05/17/2019
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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 5/17/2019, the laboratory failed to take and document corrective action for unsatisfactory proficiency testing scores for three out of four testing events (2018 testing events 1, 2 & 3) from January 2018 - May 2019. The findings include: 1. For 2018 testing event 1, the laboratory received an unsatisfactory PT score of 80% for the analyte, manual blood cell identification. 2. For 2018 testing event 2, the laboratory received an unsatisfactory PT score of 80% for the analyte, manual blood cell identification. 3. For 2018 testing event 3, the laboratory received an unsatisfactory PT score of 60% for the anlayte, hematocrit. 4. At the time of the survey, the laboratory did not have documented corrective action for the above unsatisfactory PT scores.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the FREND performance specification records and confirmed by laboratory personnel #2 (refer to the Laboratory Personnel Report), the laboratory failed to perform and verify the performance specification of reportable range for the analytes: thyroid stimulation hormone (TSH), free thyroxine (FT4) and 25-hydroxyvitamin D. The findings include: 1. The laboratory director approved the verified performance specifications of accuracy, precision, and reference range for the analytes: TSH, FT4, and 25-hydroxyvitamin D on 2/1/2018. 2. When the laboratory verified the performance specifications of accuracy, precision and reference ranges for the above analytes, they did not verify the reportable range. 3. At the time of the survey, the laboratory did not have records verifying the reportable range for the analytes: TSH, FT4, and 25-hydroxyvitamin D.