Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D1076651	10/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Clinic Pathology Laboratory, The	5950 University Avenue, West Des Moines, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at 9:53 am on 10/26 /2023, the laboratory failed to perform a self evaluation when it received five ungraded PT scores from three out of four PT testing events from 01/01/2022- 10/26 /2023. The findings include: 1. For 2022 testing event 1, the laboratory received ungraded PT test scores for the following: *HER2- A 2022: core 08 (specimen HER2-01) and core 07 (specimen HER2-02) 2. For 2022 testing event 2, the laboratory received ungraded PT test scores for the following: *HER2- B 2022: core 01 (specimen HER2-04) and core 09 (specimen HER2-04) 3. For 2023 testing event 1, the laboratory received ungraded PT test scores for the following: *HER2- A 2023: core 03 (specimen HER2-02) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores listed above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test

	results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation during a tour of the laboratory and confirmed by laboratory personnel identifier #4 (refer to the Laboratory Personnel Report) at 1:30 pm on 10/26/2023, the laboratory failed to perform twice annual comparison studies for three out of three time periods from 01/01/2022 - 10/26/2023 for the Ventana Benchmark Ultra IHC/ISH System. The findings include: 1. The laboratory performs IHC staining on two Ventana Benchmark Ultra IHC/ISH System instruments called Marvin and Marcia. 2. At the time of the survey, the laboratory did not have documentation of comparison activities performed between the two Ventana Benchmark Ultra IHC/ISH System instruments, Marvin and Marcia, from 01/01/2022 - 10/26/2023.