Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383307	08/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Clinic Laboratory, The	1215 Pleasant Street, Suite 206, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records, the laboratory's test list, observations made during the survey, and confirmed by interview with the Practice Manager at 1:55 pm on 08/19/2025, the laboratory failed to enroll in an HHS approved proficiency testing program for the analyte, troponin-I, for one out of one year from 01/01/2025- 08/19/2025. The findings include: 1. The laboratory's test list indicated the laboratory performs troponin-I testing on the Triage MeterPro test system. 2. A tour of the laboratory confirmed the presence of the Triage MeterPro test system and troponin-I test cartridges. 3. At the time of the survey, the Practice Manager confirmed the laboratory did not enroll in proficiency testing for the analyte, troponin-I, in 2024.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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 review of the laboratory's test list, American Proficiency Institute (API) proficiency testing records, observations made during the survey, and confirmed by interview with the Practice Manager at 1:55 pm on 08/19/2025, the laboratory failed to verify the accuracy of d-dimer testing performed on the Triage MeterPro test system twice annually for one out of one time period from 01/01/2025- 08/19/2025. The findings include: 1. The laboratory's test list indicated the laboratory performs d-dimer testing on the Triage MeterPro test system. 2. A tour of the laboratory confirmed the presence of the Triage MeterPro test system and d-dimer test cartridges. 3. At the time of the survey, the Practice Manager confirmed the laboratory did not enroll in proficiency testing or perform twice annual accuracy testing for d-dimer testing by another method from 01/01/2025- 08/19/2025.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 performance specification records and confirmed by interview with Technical Consultant #1 (TC #1) at 3:15 pm on 08/19/2025, the laboratory failed to verify the performance specifications of precision and reportable range prior to testing and reporting patient specimens on the Triage MeterPro test system for two out of two analytes. The findings include: 1. The laboratory began using the Triage MeterPro test system to perform troponin-I and d-dimer patient testing in December 2024. 2. Review of the Triage MeterPro verification of performance specification records indicated the laboratory failed to verify precision and reportable range for troponin-I and d-dimer testing. 3. At the time of the survey, TC #1 confirmed that the laboratory failed to have documentation of verification of the performance specifications of precision and reportable range for troponin-I and d-dimer testing.