Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2290956	09/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
The Iowa Clinic Core Laboratory	5950 University Ave Ste 270, 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 American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with the Laboratory Operations Director at 2:00 pm on 09/26/2025, the laboratory failed to perform a self evaluation when the laboratory received 15 ungraded PT scores from five out of five PT testing events from 01/01/2024- 09/26/2025. The findings include: 1. For 2024 testing event 2, the laboratory received ungraded PT test scores for the following: *2024 Immunology/ Immunohematology- Anti-CCP (specimens CCP-03 and CCP-04) *2024 Immunology/ Immunohematology- C-reactive protein (specimen CRP-03) *2024 Immunology/ Immunohematology- Thyroglobulin Ab (specimens TA-03 and TA-04) *2024 Immunology/ Immunohematology- Anti-HIV-1/2 (specimen VM-08) 2. For 2024 testing event 3, the laboratory received ungraded PT test scores for the following: *2024 Immunology/ Immunohematology- Anti-CCP (specimens CCP-05 and CCP-06) *2024 Immunology/ Immunohematology- Anti-HIV-1/2 (specimen VM-12) 3. For 2025 testing event 1, the laboratory received ungraded PT test scores for the following: *2025 Immunology/ Immunohematology- Anti-CCP (specimen CCP-01) *2025 Immunology/ Immunohematology- Anti-HIV-1/2 (specimen VM-01) 4. For 2025 testing event 2, the laboratory received ungraded PT test scores for the following: *2025 Immunology/ Immunohematology- Anti-CCP (specimen CCP-03) *2025 Immunology/ Immunohematology- Anti-HIV-1/2 (specimen VM-10) 5. For 2025 testing event 3, the laboratory received ungraded PT test scores for the

	following: *2025 Chemistry Core- Folate (specimens IA-07 and IA-09) 6. At the time of the survey, the Laboratory Operations Director confirmed the laboratory did not take and document corrective action for the ungraded PT test scores listed above.
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 American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with the Laboratory Operations Director at 2:00 pm on 09/26/2025, the laboratory failed to take and document corrective action for eight unacceptable PT scores from four out of five PT testing events from 01/01/2024-09/26/2025. The findings include: 1. For 2024 testing event 2, the laboratory received unacceptable PT test scores for the following: *2024 Chemistry Core- TIBC, measured (specimens CH-06, CH-07, and CH-09) *2024 Chemistry Core- DHEA-S (specimen IA-06) 2. For 2024 testing event 3, the laboratory received unacceptable PT test scores for the following: *2024 Chemistry Core- Insulin (specimens IAS-12) *2024 Chemistry Core- Parathyroid hormone (specimen IAS-12) 3. For 2025 testing event 1, the laboratory received unacceptable PT test scores for the following: *2025 Immunology/ Immunohematology- IGA (specimen IMP-04) 4. For 2025 testing event 2, the laboratory received unacceptable PT test scores for the following: *2025 Chemistry Core- Folate (specimen IA-08) 5. At the time of the survey, the Laboratory Operations Director confirmed the laboratory did not take and document corrective action for the unacceptable PT test scores listed above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration and calibration verification records, chemistry policies and procedures, and confirmed by interview with the Laboratory Operations Director at 1:00 pm on 09/26/2025, the laboratory failed to perform calibration verification

	procedures every six months for one out of two time periods from 11/01/2024- 09/26 /2025 for the Siemens Atellica chemistry test system. The findings include: 1. Review of the laboratory's "Atellica Calibration Verification" policy indicated calibration verification must be performed for the following analytes: albumin, alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, carbon dioxide, direct bilirubin, total bilirubin, calcium, chloride, cholesterol, creatine kinase, creatinine, gamma-glutamyl transferase, glucose, high-density lipoprotein cholesterol, hemoglobin A1C, iron, lactate dehydrogenase, lipase, magnesium, phosphorus, potassium, sodium, total protein, triglycerides, uric acid, urea nitrogen, total iron-binding capacity, urine microalbumin, urine creatinine, human chorionic gonadotropin, carcinoembryonic antigen, estradiol, ferritin, folate, free thyroxine, free triiodothyronine, follicle stimulating hormone, luteinizing hormone, B-type natriuretic peptide, prostate specific antigen, testosterone, c-reactive protein, thyroid stimulating hormone, immunoglobulin A, immunoglobulin G, rheumatoid factor, cancer antigen 125, progesterone, prolactin, complement C3, complement C4, alpha fetoprotein, anti-cyclic citrullinated peptide IGG, anti-thyroid peroxidase, antithyroglobulin, troponin I high sensitivity, cortisol, DHEA, insulin, intact parathyroid hormone, vitamin B12, and vitamin D total. 2. The laboratory performed calibration verification procedures for the analytes listed above in November 2024. 3. At the time of the survey, the Laboratory Operations Director confirmed the laboratory did not have calibration verification records which included a minimal (zero) value, a mid-point value, and maximum value for the analytes listed above for one time period between 11/01/2024-09/26/2025.