Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382707	03/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Wayne County Hospital	417 South East Street, Corydon, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by interview with General Supervisor #1 (GS #1) at 10:15 am on 03/12/2025, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for five out of six PT events from 01/01/2023 - 12/31/2024. The findings include: 1. For 2023 event 1, the laboratory director did not sign the Miscellaneous Chemistry and Core Chemistry PT attestation statements. 2. For 2023 event 2, the laboratory director did not sign the Immunology/Immunohematology and Hematology/Coagulation PT attestation statements. 3. For 2024 event 1, the laboratory director did not sign the the Miscellaneous Chemistry, Immunology/Immunohematology, and Hematology /Coagulation PT attestation statements. 4. For 2024 event 2, the laboratory director did not sign the Miscellaneous Chemistry, Immunology/Immunohematology, and Hematology/Coagulation PT attestation statements. 5. For 2024 event 3, the laboratory director did not sign the Hematology/Coagulation attestation statement. 6. At the time of the survey, GS #1 confirmed the laboratory director did not sign the PT attestation statements listed above.
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 Test List and Annual Volume form, proficiency testing records, and confirmed by interview with general supervisor #1 (GS #1) at 10: 15 am on 03/12/2025, the laboratory failed to verify the accuracy of the direct antiglobulin test (DAT) and procalcitonin testing twice annually for three out of three time periods from 01/01/2024 - 03/12/2025. The findings include: 1. The Laboratory Test List and Annual Volume form listed DAT and procalcitonin testing as testing performed by the laboratory. 2. At the time of the survey, GS #1 confirmed the laboratory did not enroll in proficiency testing or perform twice annual accuracy testing for DAT and procalcitonin testing by another method from 01/01/2024- 03/12 /2025.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by interview with General Supervisor #1 (GS #1) at 1:00 pm on 03/12/2025, the laboratory failed to perform two levels of QC at least once each day of patient testing for one out of 30 days of patient testing reviewed from 11/01/2024- 11/30/2024. The findings include: 1. The laboratory performed chemistry testing on the Ortho Vitros 7600 instrument. 2. Review of the Ortho Vitros 7600 QC records revealed that the laboratory only performed level two QC for sodium on 11/08/2024. 3. The laboratory performed and reported 32 patient sodium results on 11/08/2024. 4. At the time of the survey, GS #1 confirmed the laboratory failed to perform two levels of QC at least each day of patient testing for one out of 30 days of patient testing reviewed from 11 /01/2024- 11/30/2024.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of Ortho Vitros 7600 quality control (QC) records, the Ortho Vitros Triiodothyronine, free (FT3) Instructions for Use (IFU), and confirmed by interview with General Supervisor #1 (GS #1) at 1:00 pm on 03/12/2025, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for two out of 30 days of patient testing reviewed from 11/01/2024- 11/30/2024. The findings include: 1. The laboratory performed chemistry testing on the Ortho Vitros 7600 instrument. 2. The laboratory established a reference range of 16.57- 24.99 pg/mL for level 2 FT3 QC. 3.

	Review of level 2 FT3 QC records revealed a result of >22.78 pg/mL on the following dates: * 11/05/2024- 3 patient tests reported * 11/07/2024- 4 patient tests reported 4. The Ortho Vitros FT3 IFU listed the test's reportable range as 0.5- 22.8 pg/mL. 5. At the time of the survey, GS #1 confirmed the laboratory established a reference range for level 2 FT3 QC that exceeded the Ortho Vitros 7600 reportable range. In addition, GS #1 confirmed the laboratory did not have documented corrective action for the QC results that exceeded the Ortho Vitros 7600 FT3 reportable range on 11/05/2024 and 11/07/2024.