Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0382707	10/06/2022
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Indirect Antiglobulin Testing (Antibody Screen) procedure and patient antibody screen records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 10/4/2022, the laboratory failed to follow the laboratory's Indirect Antiglobulin Testing (Antibody Screen) procedure for one out of four patients who had a positive antibody screen from 1/1/2022 - 10/4/2022. The findings include: 1. The Indirect Antiglobulin Testing (Antibody Screen) procedure states, "Investigate any result that is interpreted as positive....Refer specimen to the blood center for antibody investigation and antibody identification. Request an antibody titer if appropriate (e.g. Anti-D in a pregnant patient)." 2. On 9/7/2022, patient identifier A had ABO grouping, D(Rho) typing and an antibody screen performed. The laboratory received a positive results for the antibody screen. 3. The laboratory did not follow the procedure and refer the specimen to the blood center for antibody investigation and antibody identification.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different

	concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 10/4/2022, the laboratory failed to perform two levels of QC for one out of 34 days of patient testing for the analyte, cholesterol from 9/1/22 - 10/4/2022. The findings include: 1. On 9/26/2022, the laboratory ran level 1 and level 3 of QC on the chemistry analzyer. 2. For the analyte cholesterol, the laboratory received an error, "No result". 3. The laboratory reran level 1 QC, but did not rerun level 3 QC. 4. Laboratory personnel #1, confirmed the laboratory only performed one level of QC for the analyte, cholesterol on 9/26/2022.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records and confirmed by testing personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 4:00 pm on 10/4/2022; the laboratory director failed to meet the responsibilities for the overall operation and administration of the laboratory by ensuring that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results (refer to D6102).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifiers #1 and #2 (refer to Laboratory Personnel Report) at approximately 4:00 pm on 10/04/2022, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel received the appropriate training for four out of 35 testing personnel. The findings include: 1. Since the last survey on 05/24/2021, the laboratory hired laboratory personnel identifiers #3, #4, #5, and #6. 2. Laboratory personnel #1 and #2 confirmed that identifiers #3 - #6 all performed patient testing. 3. At the time of the survey, the laboratory did not have training records available for testing personnel identifier #3 - #6.