Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0666786	04/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Regional Medical Center	709 West Main Street, Manchester, 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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on review of patient test reports and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 11:45 am on 04/27/2023, the laboratory failed to include the test report date for six out of nine patient test reports (patient identifiers A-F) reviewed from November 2022. The findings include: 1. The test reports for patient identifiers A-F all included specimen collection dates for testing performed. 2. Personnel identifier #13 stated that the laboratory collected and performed most testing on the same date, but not always. 3. At the time of the survey, personnel identifier #13 confirmed that the test reports for patients A-F did not include the final report date for the testing performed. B. Based on review of patient test reports, the Laboratory Test List & Annual Volume form, and confirmed by laboratory personnel identifier #13 (refer to the Laboratory Personnel Report) at approximately 1:15 pm on 04/27/2023, the laboratory failed to indicate the name and address of the testing facility for one out of nine patient test reports (patient identifier A) reviewed from November 2022. The findings include: 1. Patient identifier A's test report indicated they had the following testing performed on 11/02/2022: ABO group and D (Rho) typing, antibody screen, compatibility, and antibody identification. 2. The Laboratory Test List & Annual Volume form did not

	indicate that the laboratory performs antibody identification testing. 3. Personnel identifier #13 stated that the laboratory does not perform antibody identification testing and that all positive antibody screening tests are sent to a reference laboratory for the antibody identification testing. 4. At the time of the survey, personnel identifier #13 confirmed that the test report did not indicate the name and address of the testing facility for the antibody identification testing performed on 11/02/2022 for patient identifier A.