

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D1001298	<b>(X3) Date Survey Completed</b>  10/06/2023
<b>Name of Provider or Supplier</b>  University Of Minnesota Virology Research	<b>Street Address, City, State</b>  516 Delaware Street Se, Pwb 15-119, Minneapolis, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure Virology test result reports included four of seven required elements in 2023. Findings are as follows: 1. The laboratory performed Epstein-Barr virus antibody testing as confirmed by the Technical Supervisor (TS) during a tour of the laboratory at 1:00 p.m. on 10/05/23. 2. Gold Standard (Diamedix Immunosimplicity) EBV-VCA IgG Antibody ELISA test kits were observed as present and available for use during the tour. Testing was implemented on 08/09/23 as indicated by the TS and confirmed by laboratory records. 3. A patient test result report was not available on date of survey. The sample test report provided during survey did not include the following required items: -Two patient identifiers -The name and address of the laboratory location -The test report date 4. The laboratory was given five days to provide the test result report for patient SCR009. The TS emailed this test result report at 11:11 a.m. on 10/06/23. The test report did not include the following required items: -Two patient identifiers -The name and address of the laboratory location -The test report date -The test performed 5. In an email received at 2:49 p.m. on 10/06/23, the TS confirmed the above finding. .</p>