

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2340731	(X3) Date Survey Completed 09/08/2026
Name of Provider or Supplier Lemedix Midwest Lab Llc	Street Address, City, State 799 Roosevelt Rd, Bldg 6 - Ste 100, Glen Ellyn, IL	
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) (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: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory representative; the laboratory failed to ensure that the testing date/time on patient test reports matched the date/time that testing occurred for Polymerase Chain Reaction (PCR) testing for three of three for SARS-CoV/Influenza A/ Influenza B/Respiratory Syncytial Virus (RSV) Identification panels ran on the QuantStudio 7 Flex in the specialty of microbiology. Findings include: 1. Review of laboratory policies procedures revealed the procedure titled, "Applied Biosystems QuantStudio 7 Flex Real time PCR System Operations", which stated, under "Step 6 Data Export & post run Clean up:", "Save the complete file (.eds format) and export analytical data to the laboratory's secure network drive for secondary technical review and director sign- off." 2. Review of three of three SARS-CoV/Influenza A/ Influenza B/ RSV identification panel test documents and patient final reports found the laboratory failed to ensure the testing date/time matched the final report date/time. Specimen ID: Date/time of Testing: Date/time on Final report: 60020529N1 07/08/26/8:22 PM 07/08/26/2:22 PM 60029450Z1 08/13/26/7:47 PM 08/13/26/7:25 PM 60037401Z1 09/03/26/4:32 AM 09/02/26/10:06 PM 4. Interviews with the laboratory representative on 09/08/2026, at 3:03 PM, confirmed

the laboratory failed to ensure that the date/time on the test report matched the date /time on the final report for three of three SARS-CoV/Influenza A/ Influenza B/ RSV Identification panels ran on the QuantStudio 7 Flex.