

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2143481	(X3) Date Survey Completed 05/21/2021
Name of Provider or Supplier Premier Acute Care Services, Llc	Street Address, City, State 11073 Colonel Armistead Drive - Suite 105, Ruther Glen, VA	
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
D0000	<p>An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00051811) was conducted at Premier Acute Care Services, LLC on May 20-25, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. During the complaint investigation, the inspector found that the laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulation: D3000- 42 CFR. 493.1100 Condition Facility Administration (Reporting of SARS-CoV-2 test results).</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on a tour, interviews, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), review of policies and procedures, patient log sheet record review, and lack of documentation, the laboratory failed to report two thousand ninety (2,090) SARS-CoV-2 negative test results as required for the one hundred thirty-four (134) testing days reviewed (timeframe of January 7, 2021 to the date of the survey tour, May 20, 2021). Findings</p>

include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building (located in the back parking lot of the medical office) on 5/20/21 at approximately 1:15 PM, the inspector requested a listing of the facility's COVID-19 test methods. The office manager outlined that the laboratory utilized Access Bio CareStart COVID-19 test kits for rapid antigen testing in the drive through and also provided RightSign Covid 19 IgG/IgM and Abbott ID Now rapid COVID-19 testing in the main medical building laboratory. 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 05/20/21 revealed an EUA was granted for the test methods outlined above. The FDA listing included each manufacturer's package insert / IFU which outlined Conditions of Authorization for the Laboratory as: "All laboratories using this test must follow standard confirmatory testing and reporting guidelines according to appropriate public health authorities. Laboratories using product will have a process in place for reporting test results to healthcare providers and to public health authorities, as appropriate". 3. The inspector requested to review each of the laboratory's COVID-19 test method procedures, result logs, reporting protocols, and evidence of reporting to the state agency for the timeframe of January 7, 2021 to May 21, 2021. Documentation revealed four thousand three hundred fifty (4,350) SARS-CoV-2 patient tests were resulted from 1/7/21 to 05/20/21 and that 2,090 negative SARS-CoV-2 results were not reported to the state agency as required on 134 of 134 test days during the timeframe. The primary testing personnel stated at approximately 3:00 PM on 05/20/21: "We are in contact by telephone and fax to our county health department and report all positive COVID-19 results. We have not reported negatives. Our lab manual does not have a policy related to reporting COVID-19 results." 4. In an exit interview with the office manager on 05/25/21 at approximately 4:00 PM, the above findings were confirmed.