

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2143481	<b>(X3) Date Survey Completed</b> 04/13/2022
<b>Name of Provider or Supplier</b> Premier Acute Care Services, Llc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at Premier Acute Care Services on 04/13/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director. The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: ***REPEAT DEFICIENCY*** Based on the review of policy and procedures (P&amp;P), lack of documentation, and interview, the lab director failed to review and approve the P&amp;P after assuming the duties of lab oversight on 08/03/21 and up to the date of survey on 04/13/22. Refer to D6031.</p>
<b>D6031</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

**\*\*\*REPEAT DEFICIENCY\*\*\*** Based on the review of policy and procedures (P&P), lack of documentation, and interview, the lab director failed to review and approve 18 of 18 P&P after assuming the duties of the lab oversight on 08/03/21 and up to the date of survey on 04/13/22. Findings include: 1. Review of the P&P revealed the following: REF #0001 Regulatory Requirements, REF #0002 Competency Assessment, REF #0013 Direct Access to Patient Results, REF #0101 Inoperable System, REF #1010 Identification of Patients, REF #1012 Labeling of Specimens, REF #1035 Retention of Laboratory Records, REF #3005 FDA Mandatory Reporting of Device Related Adverse Events, REF #2018 Reagents, REF #3036 Proficiency Testing, REF #3037 Incident Management Plan, REF #5001 Standard Precautions, REF #5003 Hand Hygiene, REF #5013 Handling of Hazardous Waste, REF #9005 New Test Implementation Policy, REF #15027 Quality Control Monthly Reports, REF #1000 Test Menu, Method, and Quality Assessment Plan. The 18 P&P lacked documentation of the current lab director review and approval after assuming the duties of lab oversight on 08/03/21 and up to the date of survey on 04/13/22. 2. An exit interview with the office manager and technical consultant at 1425 confirmed the findings.