

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  41D0677950	<b>(X3) Date Survey Completed</b>  05/25/2021
<b>Name of Provider or Supplier</b>  Block Island Health Services	<b>Street Address, City, State</b>  6 Payne Road, New Shoreham, RI	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview conducted on 05/25/2021, the laboratory failed to perform calibration verification at least once every 6 months for the i-Stat cTnl (Troponin) test system as stated in their approved Quality Control Plan (QCP). Findings include: 1. Record review of the Block Island Medical Center Quality Control Plan (QCP) approved by the Laboratory Director on 2/28/2021 stated revealed "Calibration Verification: Frequency: Every 6 months with software update. On each meter prior to use". 2. Record review of 2020 and 2021 calibration verification documentation for the i-Stat cTnl revealed that the i-Stat cTnl (Troponin) calibration verification was last performed on 4/24/2020. 3. Staff interview with the Laboratory Director and Testing Personnel #1 on 5/25/2021 at 12:20 pm confirmed the above findings.</p>