

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2099227	(X3) Date Survey Completed 04/10/2023
Name of Provider or Supplier Southcoast Cardiology And Primary Care, Llc	Street Address, City, State 275 Allen Street, Suite 206, New Bedford, MA	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to include the reference ranges in the procedure manual in the specialties of Chemistry and Hematology. Findings include: 1. Record review on 3/31/2023 of the CMS form 116 section VIII, non-waived testing revealed the following non-waived tests are performed by the laboratory; red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet count, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, red cell distribution width, mean platelet volume, neutrophil percent, absolute neutrophil count,</p>

lymphocyte percent, absolute lymphocyte count, monocyte percent, absolute monocyte count, eosinophil percent, absolute eosinophil count, basophil percent, absolute basophil count, prostate specific antigen, thyroid stimulating hormone, free thyroxine, and free triiodothyronine. 2. Record review on 3/31/2023 of the laboratory's final patient test reports revealed: a. The above tests are reported on patient samples. b. The final patient test report contained reference ranges for the above tests. 3. Record review on 3/31/2023 of the laboratory's procedure manual for chemistry and hematology revealed the procedure manual did not include normal ranges for the tests indicated in #1 above. 4. Staff interview with the technical consultant on 3/31/2023 at 11:30 AM confirmed the procedure manual does not contain normal ranges for tests performed by the laboratory and reported on patient samples. 5. The laboratory performs 9,074 chemistry tests and 18,912 hematology tests annually.