

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0999179	<b>(X3) Date Survey Completed</b>  11/26/2019
<b>Name of Provider or Supplier</b>  Starling Physicians, PLLC	<b>Street Address, City, State</b>  1260 Silas Deane Hwy, Wethersfield, CT	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's personnel competency records on 11/26/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the clinical consultant and technical consultant (TC). b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the TC on 11/26/19 at 11:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> 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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to provide a complete procedure manual which includes all three phases (pre-analytical, analytical and post-analytical) of testing in the specialty of hematology. Findings include: 1. Record review on 11/26/19 of the hematology procedure manual revealed the lack of: a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection. b) Instrument maintenance requirements c) Control procedures d) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. e) The protocol for reporting critical, panic, or alert test result values f) Reference (normal) values g) Reporting of test results 2. Staff interview with the laboratory's technical consultant on 11/26/19 at 11:00 AM confirmed the above findings.. 3. The laboratory performs 54,246 tests annually in the specialty of hematology.