

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0102621	<b>(X3) Date Survey Completed</b> 03/02/2020
<b>Name of Provider or Supplier</b> Stamford Health Medical Group, Inc	<b>Street Address, City, State</b> 126 Morgan Street, Stamford, 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 3/2/2020 revealed the following: a. The laboratory did not have a policy in place to assess the competency of 8 of 8 clinical consultants and 1 technical consultant (TC). b. The laboratory did not have competency assessment documentation for the above referenced laboratory personnel. 2. Staff interview with the TC on 3/2/2020 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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish and follow the normal reference ranges for complete blood count (CBC) test results for their population. Findings include: 1. Record review of the laboratory's procedure manual (page 14) on 3/2/2020 revealed, "CBC-review Harriet Lane age specific charts posted above Horiba Micros 60." 2. Record review of final patient test report # 2073840 for CBC on 3/2/2020 revealed the reference ranges listed on the report did not match with the Harriet Lane age specific charts posted in the laboratory. 3. Staff interview with the technical consultant (TC) on 3/2/20 at 1:00 PM confirmed the following: (a) Reference ranges on the final patient report are different than the reference ranges indicated in the procedure manual. (b) The laboratory follows the reference ranges provided by the instrument manufacturer- Horiba Micros 60. 4. The laboratory performs 8,673 tests annually in the specialty of hematology.