

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0992935	<b>(X3) Date Survey Completed</b>  05/23/2023
<b>Name of Provider or Supplier</b>  Hampton Medical Care, Llc	<b>Street Address, City, State</b>  145 West Montauk Highway, Building A, Hampton Bays, NY	
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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on the review of standard operating procedures, the laboratory failed to establish written policies and procedures for specimen transportation. The practice routinely transported specimens from Hampton Medical Care located at 200 Pantigo Place, East Hampton, New York, CLIA: 33D0859130. Confirmed findings on an interview with the technical consultant on 5/23/2023, at approximately 12:00 P.M.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on lack of calibration records, the laboratory failed to perform instrument and</p>

equipment calibration post expiration dates. Confirmed findings on an interview with technical consultant on 5/23/2023, at approximately 11:30 A.M. Findings: 1. No documentation of calibration for the Acurite Thermometer (no serial number available) used to measure the temperatures of the lab refrigerator, freezer, and refrigerator in basement utilized to store quality control material. 2. The most recent calibration for the pipette (no serial number available) utilized for specimen processing. expired on 4/2018. 3. No documentation of calibration for the Acurite Thermometer (no serial number available) used to monitor the room temperature and humidity where specimen processing occurred.