

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2277418	<b>(X3) Date Survey Completed</b>  08/27/2024
<b>Name of Provider or Supplier</b>  City Medical Of Ues	<b>Street Address, City, State</b>  901 Franklin Avenue, Garden City, 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 review of laboratory standard operating procedures (SOPs) as well as interview with the Testing Person (TP), the laboratory failed to draft, approve written policies and procedures for specimen collection, labeling, storage, transportation, acceptability, and rejection. FINDINGS: 1. The current, approved SOPs did not include instructions for patient specimen collection, labeling, storage, transportation, acceptability, rejection, and distribution to reference laboratories. 2. The TP confirmed the findings on August 27, 2024, at approximately 11:30 A.M.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory's humidity log, cryostat maintenance records, as well as interview with the Practice Manager (PM), the laboratory failed to comply with cryostat manufacturer's humidity specifications. FINDINGS: 1. The cryostat manufacturer's specifications limited relative humidity to sixty percent. 2.

Documented laboratory humidity was out of range from August 2023 through survey date. 3. There was no documentation of cryostat maintenance from August 2023 through survey date. 4. The PM confirmed the findings August 27, 2024, at approximately 12:00 P.M.