Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0143708	06/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
City Medical Of Upper East Side	2035 Lakeville Road, Suite 104 & 206, New Hyde Park, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a quality control (QC) record, the laboratory failed to follow the manufacturer's instruction for testing and documenting QC material for the Siemens' Multistix reagent strips when a new vial is opened or every 30 days. Findings: 1. QC missing between 9/25/2020 through 11/3/2020 and 5/7/2021 through 11/16/2021. 2. Confirmed on an interview with technical consultant on 6/21/2022 about 12pm. 3. Approximately 100 patients test performed during this period.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on the review of Freezer #1 and #2 temperature log, the laboratory failed to

	maintain established temperature range of Bio-Rad Control Leve 1 and Level 1 range of -20C to -70C. Finding: 1. Freezer #1 out of range 5/2020 through survey date. 2. Freezer #2 out of range 1/2020 through survey date. 3. Confirmed on an interview with technical consultant on 6/21/2022 about 3:30pm
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of Siemens Multistix quality control records, the laboratory failed to review quality control material for expired dates. Finding: 1. 12/9/2020 and 1/12/2021 used Lot # 447808 Expiration date 11/30/2020 2. 5/17/2022 and 6/17/2022 used Lot#73040B Expiration date 4/30/2022 3. Confirmed on an interview with technical consultant on 6/21/2022 about 12:30pm
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance reports, the laboratory director failed to maintain all phases for the general laboratory system. Refer to D1001, D5413, D5417,