Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0143708	10/30/2019
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
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 a surveyor's review of the Quality Control (QC) records and an interview with the technical consultant, the laboratory failed to discontinue the use of the expired QC materials. FINDINGS: 1. On October 30, 2019 at approximately 12:30 PM the technical consultant confirmed surveyor's findings that the laboratory used expired calibration materials for the following analytes: A. Parathyroid Hormone (PTH) was tested on 6/14/19 using the QC materials lot # 010181000 expired 6/7/19 B. Total PSA was tested on 6/17/19 using the QC materials lot # 89458FN00 expired 6 /14/19 2. Approximately 25 patients were tested for the above analytes using the expired QC materials during the above time frames. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON AUGUST 6, 2019.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory's equipment maintenance records and an

	interview with the technical consultant and the testing person, the laboratory failed to follow the manufacturer's requirement to calibrate the pipette annually. Findings: On October 30, 2019 at approximately 12:30 PM the technical consultant confirmed surveyor's finding that the laboratory failed to follow the manufacturer's requirement to calibrate the 500 pipette used for QC and reagent preparation in calendar year 2018 and up to survey date.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's calibration verification records and an interview with the laboratory technical consultant and the testing person, the laboratory failed to perform calibration verification at least once every six months for endocrinology testing on the Abbott Architect Plus analyzer in calendar year 2018 and up to survey date. FINDINGS: At approximately 12:30 PM on October 30, 2019, the technical consultant confirmed that the only calibration verification records available for the Abbott Architect Plus was for September 2018 and July 2019. The laboratory had not performed calibration verification for all analytes on the Abbott Architect Plus at least once every six months as required. Approximately 300 patients were tested during this time period. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON AUGUST 6, 2019.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of the Cell Dyn Emerald hematology QC records, manufacturer's QC requirements, the laboratory's QC procedure and an interview with the technical consultant and the testing person, the laboratory failed to follow their established written QC policy and perform three levels of controls each day of patient testing on September 8, 2018. FINDINGS: 1. The technical consultant confirmed on October 30, 2019 at approximately 12:30 PM the surveyor's findings that the laboratory failed to perform three levels of hematology QC following calibration and prior to patient testing on September 8, 2018. 2. Approximately 20 patients' samples were tested and reported for hematology on September 8, 2018.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of Quality Control (QC) records and an interview with the technical consultant and the testing person, the laboratory failed to program the manufacturer expected ranges, as defined on the QC assay sheets, into the Beckman Olympus AU 480 analyzer for chemistry testing from September 2019 through the survey date. FINDINGS: A) On 10/30/2019 at approximately 1:00 PM, the technical consultant and the testing person confirmed the surveyor's review of QC records finding that the laboratory failed to program the established QC ranges and expected means into the new Beckman Olympus AU 480 analyzer for the chemistry tests performed. B) Without the established QC limits, the surveyor could not determine if the quality control results were within the acceptable ranges for the chemistry analytes tested on the Beckman Olympus AU 480 analyzer. C) Approximately 35 patients' specimens were tested and reported for chemistry during this time period. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON AUGUST 6, 2019.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the technical consultant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on August 6, 2018; 2. Maintained the laboratory's QC program for chemistry, endocrinology, and hematology. Refer to D6020; and, 3. Maintained the laboratory's established QA program for all phases of laboratory testing. Refer to D6021. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON AUGUST 6, 2019.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's quality control (QC) records and confirmed in an interview at the time of this survey with the technical consultant, the laboratory director failed to ensure that the QC program for hematology, endocrinology and chemistry testing was maintained to assure quality of laboratory services. Refer to: D5439, D5441, D5469 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON AUGUST 6, 2019.
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 a review of the laboratory's quality assessment (QA) program and confirmed in an interview with the technical consultant at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. D5417, D5429 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON AUGUST 6, 2019.