Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0143708	08/06/2018
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 surveyor's review of the manufacturer's packet inserts for the Siemens Multistix and interview with the technical consultant, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the Siemens Multistix from January 2017 through April 2018. FINDINGS: 1. The packet insert for the Siemens Multistix requires that external controls be performed with each new vial of Multistix opened. On August 6, 2018 at approximately 1:30 PM the technical consultant confirmed surveyor's findings that documentation for the required external control testing was not available the Siemens Multistix from January 2017 through April 2018. 2. Approximately 200 patients specimens were tested and reported for urinalysis during the above time frame.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by:

	Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) test reports, the laboratory failed to successfully participate in a PT program approved by the Centers for Medicare and Medicaid Services (CMS) for the test analyte Parathyroid Hormone (PTH). The following scores were assigned: Parathyroid Hormone: 2017 first event = 67% 2017 second event = 33% 2018 first event = 100% (an artificial 100% was assigned) This is considered unsuccessful PT performance.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the technical consultant, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2016 third event: BNP = 50% Chloride = 80% Potassium = 80% Granulocytes = 80% Lymphocytes = 80% 2017 first event: Thyroid Stimulating Hormone (TSH) = 80% Chloride = 60% Sodium = 60% 2017 second event: Platelets = 80% Red Blood Cells = 80% CO2 = 80% 2018 first event: BNP = 50%
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a surveyor review of the Quality Assurance (QA) records and an interview with the technical consultant, the laboratory failed to verify accuracy of interpretation of Allergy testing twice in calendar year 2017 and up to survey date. FINDINGS: The technical consultant confirmed on August 6, 2018 at approximately 1:30 PM that the accuracy of Allergy testing for 36 allergens was not performed in calendar year 2017. Approximately 31 patient specimens were tested and reported for allergy during this time period.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor's review of records and an interview with the technical consultant,

	the laboratory failed to: 1. Ensure that a comprehensive procedure manual is available for all aspect of the testing process. Refer to D5403; 2. Ensure that the laboratory discontinued the use of expired QC and calibrator materials. Refer to D5417; 3. Ensure that the laboratory followed the manufacturer maintenance requirement. Refer to D5429; 4. Perform and document calibration for hematology. Refer to D5437; 5. Perform and document calibration verification for analytes with less than 3 point calibrators. Refer to D5439; 7. Perform and document QC for Immunology. Refer to D5449; 8. Perform and document lot to lot QC verification. D5469.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the technical consultant, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1. Procedure describing the laboratory's turnaround time for endocrinology, immunology, chemistry and hematology testing from sample collection to processing and to when final results are entered into the patients' charts; 2. A procedure describing a twice per year verification system for the non-regulated allergy testing.
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 calibration records and an interview with the technical consultant, the laboratory failed to discontinue the use of the expired calibration materials. FINDINGS: 1. On August 6, 2018 at approximately 1:00 PM the technical consultant confirmed surveyor's findings that the laboratory used expired

	calibration materials for the following chemistry and endocrinology analytes: A. From June 3, 2017 through September 2017 Digoxin was calibrated using calibrator lot # 00515L000 expired 6/2/17 B. From September 2017 through January 2018 TSH was calibrated using calibrator lot # 60373U00 expired 5/4/17 C. From June 2017 through March 2018 HgbA1C was calibrated using calibrator lot # 802909058 expired 5/9/17 D. From December 2017 through April 2018 PSA was calibrated using calibrator lot # 70367FN00 expired 11/1/17 E. From June 2017 through June 2018 PTH was calibrated using calibrator lot # 00516H000 expired 5/5/17 F. From May 2018 through June 2018 TSH was calibrated using calibrator lot # 75159U100 expired 4/24 /18 G. From June 8, 2017 through July 2018 BNP was calibrated using calibrator lot # 44K62818, expired 6/7/17 H. From December 2, 2017 through July 2018 FT4 was calibrated using calibrator lot # 65446U100 expired 12/1/17 2. On August 6, 2018 at approximately 1:30 PM the technical consultant confirmed surveyor's findings that the laboratory used expired Quality Control (QC) materials for the following endocrinology analytes: A. TSH was tested from 2/7/18 through 4/18 using the QC materials lot #72219U100 expired 2/6/18 B. PSA was tested from 1/12/18 through 2 /2018 using the QCmaterials lot # 73121FN00 expired 1/11/18 C. PTH was tested from 6/9/17 through 2/2018 using the QC materials lot # 015161000 expired 6/8/17 D. Vit D was tested from 2/19/18 to April 2018 using the QC materials lot #710844100 expired 2/18/18 3. Approximately 100 patients were tested for the above analytes using the expired calibration materials during the above time frame and Approximately 200 patients were tested for the above analytes using the expired QC materials during the above time frame.
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 maintenance policies and maintenance records for the Abbott Architect Plus analyzer and confirmed in an interview with the technical consultant, the laboratory failed to follow the manufacturer maintenance requirements. FINDINGS: At approximately 12:00 PM on August 6, 2018 the technical consultant confirmed surveyor's findings that the laboratory failed to perform and document routine and preventive maintenance as required by the manufacturer of the Abbott Architect Plus analyzer from June 2017 through February 2018.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor's review of hematology calibration records and interview with the technical consultant, calibration of the hematology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. The laboratory is using the Cell Dyn Emerald analyzer. The laboratory's calibration policy and the manufacturer of the hematology analyzer require analyzer calibration every six months. 2. On August 6, 2018 at approximately 1:00 PM the technical consultant confirmed that the documentation of the Cell Dyn Emerald analyzer calibration available for review was for calibration performed on 3/5/17, 4/28/17 and 1/9/18. The hematology analyzer was therefore out of calibration from 10/29/17 through 1/8/18 and from 7/10/18 through the survey date. 3. Approximately 400 patient specimens were tested and reported for hematology during the above time period when analyzer was out of calibration.
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 2017 and up to survey date. FINDINGS: At approximately 1:00 PM on August 6, 2018, the technical consultant confirmed the laboratory had not performed calibration verification on the Abbott Architect Plus for analytes, Prostate Serum Antigen (PSA) and Thyroid-Stimulating Hormone (TSH) with less than three point calibrators. Approximately 300 patients were tested during this time period.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory failed to perform and document the positive and negative controls with each patient test run for the Allergy testing from January 2017 through April 2018. FINDINGS: 1. The technical consultant confirmed on August 6, 2018 at 1: 00 PM that the quality control records for the Allergy testing were not available for review at survey for 36 allergens tested on the Hitachi CLA-1 analyzer from January 2017 through April 2018. 2. No records of Luminometer testing available from January 2017 through April 2018. 3. Approximately 40 patient samples were tested & reported for Allergy during the above time frame.
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 laboratory QC records and an interview with the technical consultant, the laboratory failed to perform and document lot to lot verification of Abbott Architect Plus and Alfa Wasserman analyzers assayed controls. Findings: At approximately 12:00 PM on August 6, 2018, the technical consultant confirmed that the laboratory had not verified assayed endocrinology and chemistry QC materials from January 2017 to June 7, 2018.
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 findings and interview with the laboratory technical consultant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. successfully participate in PT. Refer to D6016 2. maintained the laboratory's QC program for hematology; chemistry, immunology and endocrinology, refer to D6020. 3. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the surveyor's review of the API PT program records and confirmed with the technical consultant, the laboratory director failed to ensure that the laboratory successfully participated in a PT program for Endocrinology. Refer to: D2107
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: D1001, D5437, D5439, D5449, D5469
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 quality assessment records (QA), and interview with the technical consultant, the laboratory director failed to follow the laboratory's QA procedures. Findings Include: At approximately 1:00 PM on August 6, 2018, the technical consultant confirmed that although the QA reviews were performed by the laboratory's technical consultant, the laboratory failed to ensure that actions were taken to prevent recurrence of the original problems. Refer to D5211, D5217, D5403, D5417, D5429