Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2006766	08/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Manhattan Endocrinology And Metabolism Pc	325 East 79th Street, Suite 1 A, New York, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory policies/procedures, annual competency records and an interview with the technical consultant and the laborary testing person, the laboratory failed to have a complete policy and procedure for personnel competency. Finding Include: It was confirmed by the technical consultant and the laboratory testing person on August 9, 2018, at approximately 11:30 am that the laboratory failed to have a complete written procedure for annual competency to include direct observation of routine patient test performance which is one of six required components to assess the testing personnel's competency annually.
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 review of calibration records and an interview with the technical consultant and the laboratory testing person, the laboratory failed to calibrate the hematology analyzer every six months in year 2016 through 2017. Findings Include: It was confirmed with the technical consultant and the laboratory testing person on August 9, 2018 at approximately 12:30 pm that, 1. Failed to maintain their plan of correction (POC) from the survey of July 25, 2016; 2. The Manufacturer of the Coulter AcT Diff 2 requires that calibration be performed every six months; 3. Calibration was performed on July 22, 2016 and October 17, 2017 and March 27, 2018; 4. The Coulter AcT Diff 2 was out of calibration from January 23, 2017 to October 23, 2017. Approximately 720 patient specimens were tested and reported for hematology testing when calibration was not performed. This is a repeat citation from the survey of July 25, 2016.
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 a review of records and an interview with the technical consultant and laboratory testing person, the laboratory failed to perform calibration verification for all analytes performed on the chemistry and endocrinology instruments, the Ace Alera, Bio Rad D10 and the Immulite. Finding Include: It was confirmed with the technical consultant and laboratory testing person on August 9, 2018 at approximately 12:30 pm that the laboratory: 1. Failed to maintain their plan of correction (POC) from the survey of July 25, 2016; 2. Failed to follow the manufacturer and regulatory requirements for performing calibration verification every six months; 3. Calibration verification was last performed on January 27, 2016 on all three instruments. Calibration verification was due in July 2016, January 2017 and July 2017. The three laboratory instruments were out of calibration verification for 13 months. 4. Approximately 900 patients samples were tested and results were reported during the

	time the Ace Alera, D10 and Immulite analyzers were out of calibration. This is a repeat citation from the survey of July 25, 2016.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a review of the Quality Assessment (QA) policy and procedure, lack of QA reviews and an interview with the technical consultant and the laboratory testing person, the laboratory failed to follow their QA policy and perform monthly QA reviews from August 2016 through July 2017.
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 review of laboratory records and an interview with the technical consultant and the laboratory testing person, the laboratory director failed to ensure that the QC program was maintained for hematology, chemistry and endocrinology testing. Refer to D5437 and D5439 This is a repeat citation from the survey of July 25, 2016.
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 QA procedures, lack of QA reviews and an interview with the technical consultant and the laboratory testing person, the laboratory director failed to ensure that the general, pre and post analytical part of the QA systems were maintained. Refer to D5893.