Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0142257	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Rockland Endocrine & Diabetes Services Pc	**Street Address, City, State** 156 Route 59, Unit C - 1, Suffern, 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
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 review of the laboratory procedure manual and an interview with the laboratory manager, the laboratory failed to have a complete procedure manual to include a procedure for lot to lot verification of new control material used on the Pentra AU 480 chemistry analyzer, the Access 2 endocrinology analyzer, and the ABX Micros 60 hematology analyzer.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of quality assurance (QA) procedure and an interview with the laboratory manager, the laboratory failed to have a mechanism in place to verify the accuracy of their LIS system transfer of data. Finding include: It was confirmed with the laboratory manager at approximately 1:30 pm that the laboratory failed to have a mechanism in place to periodically verify the accuracy of the calculated data, results sent to the interfaced system and patient data for Glomerular Filtration Rate (GFR) and low-density lipoprotein (LDL).
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 lack of procedures and an interview with the laboratory manager, the laboratory failed to 1) have a procedure in place for lot to lot verification and 2) a procedure/mechanism for the LIS sytem which performs calculations for QC and patient data. Refer to D5403 and D5891