Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0142257	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Rockland Endocrine & Diabetes Services Pc	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 direct observations as well as lack of procedures and records, the laboratory failed to draft, approve, and maintain instructions for removal of expired patient specimen collection materials from inventory. FINDINGS: 1. The surveyor's observations in the patient specimen collection rooms confirmed on October 19, 2023, at approximately 1:00 P.M. that the current Rockland Endocrine & Diabetes Services, PC standard operating procedures did not include written, approved instructions for removal from inventory expired Becton Dickinson phlebotomy tubes utilized for collection of patient specimens.

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 direct observations and interview with the phlebotomist, the laboratory failed to remove from inventory expired patient specimen collection materials as required. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on October 19th, 2023, at approximately 1:00 P.M. the following patient specimen processing materials were not removed from inventory: a. Becton Dickenson, Lavender; Expiration: August 31, 2023; Stored in specimen collection rooms. b. Becton Dickenson, Marble SST; Expiration: August 31, 2023; Stored in specimen collection rooms. 2. The phlebotomist confirmed on October 19th, 2023, at approximately 1:00 P.M. that the respective expired patient specimen processing materials were not utilized for patient specimen processing.
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 review of the maintenance log, the TOSOH G8 instruction manual, and interview with the laboratory supervisor (LS), the laboratory failed to perform the required filter change at six month intervals. FINDINGS: 1. The surveyor's observations in the laboratory confirmed on October 19th, 2023, at approximately 12: 00 P.M. that the required six month maintenance filter change was not documented in the instrument's logbook from 2022 through the survey date. 2. This is contrary to instructions indicated in the TOSOH G8 instructions. 3. After consulting with the service engineer, the LS confirmed on October 23rd, 2023, at approximately 2:00 P. M. that filter changes must be performed every six months.