Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0240409	03/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Raleigh Endocrine Associates	2709 Blue Ridge Road, Suite 320, Raleigh, NC	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of CMS (Centers for Medicare and Medicaid Services) Casper 155D report, review of 2018 and 2019 AAFP (American Academy of Family Physicians) proficiency testing records, and staff interview 3/10/20, the laboratory failed to retain all proficiency testing records for at least two years. The laboratory's "PROFICIENCY TESTING" policy states "... The completed result form should be reviewed and signed by the laboratory director and kept for two years. ... Have the laboratory director sign all documentation and keep records for two years. ..." Review of the CMS Casper 155D report revealed the laboratory participated in proficiency testing for the 2019 3rd test event (AAFP 2019-C). Review of 2018 and 2019 AAFP proficiency testing records revealed there were no records available for review for the AAFP 2019-C test event, including signed attestation statements, report forms, and graded results. During interview at approximately 10:50 a.m., the IT (information technology) Liaison stated she was unsure where the records might be if they were not in the notebook with the other proficiency testing records.
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 review of 2019 Roche Cobas e411 calibration verification records and review of the manufacturer's product insert 3/10/20, the laboratory failed to discard calibration verification linearity material that had exceeded the expiration date. Findings: Review of the calibration verification linearity records revealed linearity was performed on 1/7/19 for the following analytes: T3 (Triiodothyronine), FT4 (free thyroxine), PSA (prostate specific antigen), and TSH (thyroid stimulating hormone). Review of the calibration verification linearity report and AUDIT MicroControls Linearity FD Immunoassay product insert revealed the Linearity FD Immunoassay material, lot #06605, expired on 10/24/18 and was used for the calibration verification on 1/7/19.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and review of 2018 and 2019 Roche Cobas e411 and Envoy 500+ QC (Quality Control) records 3/10/20, the laboratory failed to ensure QC was acceptable before reporting patient test results. Findings: 1. The laboratory's "IN-HOUSE QUALITY CONTROL PROTOCOL" states for the Roche Cobas e411, "1 High and 1 Low control ran every testing day or after any instrument malfunction. With every new lot number. After every calibration. ... **NEVER RELEASE PATIENT RESULTS WHEN QC IS NOT IN RANGE!!**" Review of the Roche Cobas e411 QC records revealed: a. Bio-Rad Liquichek Specialty Immunoassay Level 3 QC results for Vitamin D were out of acceptable range on 16 days: 8/10/18, 8/3/18, 8/14/18, 8/17/18, 5/7/19, 5/10/19, 5/15/19, 5/23/19,5/24/19, 6/4/19, 6/5/19, 6/6/19, 6/7/19, 6/12/19, 6/13/19, and 6/14/19. Additional QC documentation received from the IT (information technology) Liaison by email on 3/19/20 revealed level 2 and level 3 QC results were out of acceptable range for Vitamin D on 11/20/19. The laboratory was unable to determine the number of patients tested on the days when QC was outside the acceptable limits for Vitamin D. b. Bio-Rad Lyphochek Immunoassay Level 1 QC results for FT4 (free thyroxine) were out of acceptable range on 3 days: 11/14/18, 11/15/18, and 11/20/18. Additional QC documentation received by email from the IT Liaison on 3/19/20 revealed level 1 QC was out of acceptable range for FT4 on 11/14/19. The laboratory was unable to determine the number of patients tested on the days when QC was outside the acceptable limits for FT4. c. Bio-Rad Lyphochek Immunoassay Level 3 was out of acceptable range for TSH (thyroid stimulating hormone) on 1/29/19. The laboratory was unable to determine the number of patients tested on the day when QC was outside the acceptable limits for TSH. 2. The laboratory's "IN-HOUSE QUALITY CONTROL PROTOCOL" states for the Envoy 500+, "1 High and 1 Low control ran every testing day or with any new lot number. After every calibration. ISE is calibrated and qc'd every 4 hours. ... **NEVER RELEASE PATIENT RESULTS WHEN QC IS NOT IN RANGE!!**" Review of the Envoy 500+ QC records revealed Bio-Rad Liquichek Levels 1 and 2 were out of acceptable range on 7/2/19 for ALP (Alkaline Phosphatase). The laboratory was unable to determine the number of patients tested on the day when QC was outside the acceptable limits for ALP.

D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2018 and 2019 Roche Cobas e411 and Envoy 500+ QC (Quality Control) records, and review of 2018 and 2019 QA (Quality Assessment) records 3/10/20, the laboratory failed to take and document corrective action when QC was outside the acceptable limits. Findings: The laboratory's "IN-HOUSE QUALITY CONTROL PROTOCOL" states "... WHEN QC IS OUT ON ANY INSTRUMENT, FOLLOW THIS PROCEDURE: CHECK ALL EXPIRATION DATES AND RERUN QC IF DATES ARE IN. IF QC IS STILL OUT, PREPARE A NEW BATCH AND RUN. IF NEW BATCH IS OUT, PREPARE A NEW LOT# AND RUN. IF NEW LOT# IS OUT, CALL THE INSTRUMENT'S 800# FOR FURTHER INSTRUCTIONS. IF NECESSARY, SEND PATIENT SAMPLES TO (an outside laboratory) FOR RESULTING. **NEVER RELEASE PATIENT RESULTS WHEN QC IS NOT IN RANGE!!**" Review of 2018 and 2019 Roche Cobas e411 and Envoy 500+ QC records revealed corrective action policies were not followed when QC was outside the acceptable limits. There was no documentation that QC was rerun, that a new lot number of control material was prepared and tested, or that the manufacturer was contacted on days when QC was outside acceptable limits (see D5481). Notations in the 2018 and 2019 QA records included the following examples: "It is unclear if patients were adversely affected"; "Patients adversely affected could not be determined due to sample unavailability." There was no documentation that patient results were not reported or that patient specimens were sent to an outside laboratory for testing when QC was outside acceptable limits.
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 review of 2018 and 2019 laboratory records 3/10/20, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure the quality control policy was followed to ensure the accuracy of patient test results (see D6020). 2. The laboratory director failed to ensure corrective action was taken and documented for quality control results outside the acceptable limits (see D6024). 3. The laboratory director failed to ensure patient test results were reported only when the system was functioning properly (see D6025). 4. The laboratory director failed to ensure testing personnel met the education requirements to perform moderate complexity testing prior to testing patient specimens (see D6029).
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 the laboratory's policies and procedures, review of 2018 and 2019 Roche Cobas e411 and Envoy 500+ quality control records 3/10/20, the laboratory director failed to ensure the laboratory's QC (quality control) policy was followed to assure the accuracy of patient test results. Review of the Roche Cobas e411 and Envoy 500+ QC records revealed QC results were outside the acceptable limits for Vitamin D, FT4 (fee thyroxine), TSH (thyroid stimulating hormone), and ALP (alkaline phosphatase) on days when patients were tested. The laboratory was unable to determine the number of patients tested on the days when QC was outside the acceptable limits (see D5481).
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2018 and 2019 Roche Cobas e411 and Envoy 500+ QC (Quality Control) records, and review of 2018 and 2019 QA (Quality Assessment) records 3/10/20, the laboratory director failed to ensure corrective action was taken and documented when QC was outside the acceptable range. There was no documentation that quality control was rerun, that a new lot number of control material was prepared and tested, or that the manufacturer was contacted on days when QC was outside acceptable limits. There was no documentation that patient results were not reported or that patient specimens were sent to an outside laboratory for testing when QC was outside acceptable limits. (see D5779).
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the

	system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2019 calibration records, and review of 2018 and 2019 QC (quality control) records 3/10 /20, the laboratory director failed to ensure patient results were reported only when the system was functioning properly. Findings: 1. The laboratory used expired linearity material to calibrate the Roche Cobas e411 analyzer 1/7/19 (see D5417). 2. The laboratory failed to ensure QC results were acceptable prior to reporting patient test results (see D5481).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview 3/10/20, the laboratory director failed to ensure 1 of 2 testing personnel (TP #2) met the education requirements to perform moderate complexity testing prior to testing patient specimens. Review of personnel records for TP #2 revealed: 1. A resume which stated "OBJECTIVE: To secure a stable position as a Certified Medical Lab Technician (MLT) where I can utilize my extensive background training and experience to process and distribute laboratory samples." There were no education credentials for TP #2 available for review during the survey. 2. TP #2 was hired 9/24/19. Initial training for TP #2 was documented on the Cobas e411 and the Envoy 500+ by the technical consultant on 10/15/19. The training records were signed by the laboratory director 10/17/19 to indicate the training was complete and TP #2 was approved to perform patient testing. During interview at approximately 1:40 p.m. the IT (information technology) Liaison stated that there were no other records available for TP #2.