

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0240409	(X3) Date Survey Completed 07/24/2018
Name of Provider or Supplier Raleigh Endocrine Associates	Street Address, City, State 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with TP (testing personnel) 7/24/18, the laboratory failed to establish a written policy for specimen labeling. The laboratory's "VENIPUNCTURE PROCEDURE" states "... PERFORMANCE OF A VENIPUNCTURE: ... Identify the patient correctly. ... Mix and label all appropriate tubes." The procedure does not indicate the information included on the label, and does not indicate whether labels are computer-generated or handwritten. During interview at approximately 3:20 p.m., TP #1 confirmed that the laboratory's venipuncture procedure did not indicate the information that should be included on specimen labels.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in</p>

electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of manufacturers' instructions and review of temperature logs 7/24/18, the laboratory failed to establish acceptable ranges for room temperature and freezer temperature that were consistent with manufacturers' requirements. Findings: 1. Room Temperature The Cobas ProCell product insert states "... Storage and stability Store at 15-25 degrees C. ..." The Cobas ProCell M product insert states "... Storage and stability Store at 15-25 degrees C. ..." Review of the laboratory's temperature logs revealed the acceptable range for room temperature was listed as 18-30 degrees C (Celsius). 2. Freezer Temperature The BIO-RAD Liquichek Specialty Immunoassay Control product insert states "... This product will be stable until the expiration date when stored unopened at -20 to -70 degrees C. ..." Review of the laboratory's temperature logs revealed the acceptable range for freezer temperature was listed as -25 +/- 6 degrees C.

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 surveyor observation and testing personnel (TP) interview 07/24/18, the laboratory failed to discard diluent that had exceeded the expiration date. At approximately 2:00 p.m. the surveyor observed 1 bottle of Roche-Cobas Diluent Universal, Lot #180-209-02, expiration date 6/18, on the shelf in the door of the laboratory's refrigerator, available for use. During interview at approximately 2:00 p.m., TP #1 verified the diluent had expired and immediately disposed of the diluent.

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 manufacturer's instructions, review of chemistry analyzer maintenance records and testing personnel (TP) interview 07/24/18, the laboratory failed to perform and/or document maintenance for the Vital Diagnostics Envoy 500+ chemistry analyzer and the Siemens DCA Vantage analyzer at the frequency specified by the manufacturer. 1. Review of manufacturer's instructions for the Vital Diagnostics Envoy 500+ chemistry analyzer pages 7-5 and 7-6 revealed "Weekly... Wipe the sample needles....Perform a Shutdown....Extra Wash Cuvettes....". Review of 2018 maintenance records for the Vital Diagnostics Envoy 500+ chemistry analyzer revealed the laboratory failed to document and/or perform weekly maintenance for 1 week in March, 3 weeks in April and 3 weeks in May of 2018. Interview with TP #1 at approximately 1:00 p.m. confirmed the laboratory had failed

to document and/or perform the weekly maintenance of the Vital Diagnostics Envoy 500+ chemistry analyzer as required by the manufacturer. He stated he was sure the maintenance had been performed, but it had not been documented on the maintenance records. 2. The laboratory performs microalbumin and creatinine testing on 1 Siemens DCA Vantage chemistry analyzer and glycated hemoglobin testing on 2 Siemens DCA Vantage chemistry analyzers. Review of manufacturer's instructions for the Siemens DCA Vantage chemistry analyzer page 97 revealed "...Maintenance Schedule...Weekly...Cleaning the Onboard Barcode Reader Window...Cleaning the Exterior...Quarterly...Removing and Cleaning the Cartridge Spring and Cartridge Area...Changing the Air Filter...Optical Test..." Review of 2017 and 2018 maintenance records for the 3 Siemens DCA Vantage chemistry analyzers revealed the laboratory had documented maintenance for the 2 analyzers that performed glycated hemoglobin testing, but failed to document maintenance for the 1 analyzer that performs microalbumin and creatinine testing. Interview with TP #1 at approximately 1:00 p.m. confirmed the laboratory had failed to document and/or perform the required maintenance for the 1 Siemens DCA Vantage chemistry analyzer that performs microalbumin and creatinine testing. He stated he was sure the maintenance was being performed, but it had not been documented.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
 Based on review of manufacturer's instructions, review of the laboratory's 2017 and 2018 temperature logs, and review of quality assessment records 7/24/18, the laboratory failed to take and document corrective action for freezer temperatures outside the acceptable range for storage of the BIO-RAD Liquichek Specialty Immunoassay Control material 127 of 185 days from October 1, 2017 - June 30, 2018. Findings: The BIO-RAD Liquichek Specialty Immunoassay Control product insert states "... This product will be stable until the expiration date when stored unopened at -20 to -70 degrees C. ..." Review of the laboratory's temperature logs revealed the acceptable range for freezer temperature was listed as -25 +/- 6 degrees C (Celsius). Review of 2017 and 2018 temperature logs revealed freezer temperatures outside the manufacturer's acceptable limits for storage of the BIO-RAD Liquichek Specialty Immunoassay Control material with no corrective action documented for: 1. 12 of 21 days in October 2017; 2. 14 of 20 days in November 2017; 3. 12 of 19 days in December 2017; 4. 13 of 21 days in January 2018; 5. 16 of 20 days in February 2018; 6. 15 of 21 days in March 2018; 7. 16 of 21 days in April 2018; 8. 14 of 22 days in May 2018; 9. 14 of 20 days in June 2018. Review of the laboratory's "QA TRACKING SHEET TEMPERATURE AND HUMIDITY LOGS" for January - June 2018 revealed the following questions: "Were freezer temperatures recorded each day of testing?" "Were values outside acceptable range(s) recorded?" "If so, was appropriate remedial action taken and documented?" The laboratory's responses indicated there were no values outside the acceptable range, so remedial action was "N/A" (not applicable).

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records, review of testing personnel competency records and testing personnel (TP) interview 07/24/18, the technical consultant (laboratory director) failed to evaluate the competency of 2 of 2 testing personnel in 2018. Review of laboratory personnel records revealed TP #1, and TP #2 do not meet the educational requirements to serve as technical consultants for the laboratory. Review of laboratory personnel records revealed the laboratory director is the only personnel that does meet the educational requirements to serve as the technical consultant for the laboratory. Review of 2018 TP competency records revealed TP #1 had evaluated the competency of TP #2 on 6/25/18, and TP #2 had evaluated the competency of TP #1 on 7/21/18. The technical consultant (laboratory director) failed to evaluate the competency of TP #1 and TP #2 for 2018. Interview with TP #1, at approximately 11:00 a.m., confirmed the technical consultant (laboratory director) had not assessed the competency for 2 of 2 testing personnel. TP #1 stated he was unaware that the laboratory director was the only personnel qualified to assess testing personnel competency.