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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 49D1029632 | (X3) Date Survey Completed 05/14/2021 |
| Name of Provider or Supplier Virginia Endocrinology & Osteoporosis Center | Street Address, City, State 2384 Colony Crossing Place, Midlothian, VA | |
| 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 |
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| D0000 | An announced CLIA recertification survey was conducted at Virginia Endocrinology on May 14, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview and initial virtual record review on 5/10/2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows: |
| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on a review of procedures, manufacturer package insert, chemistry analyzer calibration verification records, lack of documentation, and an interview, the laboratory failed to document the Beckman Coulter Access 2 analyzer's Thyroid Uptake (TU) calibration verification twice annually in calendar year 2020. Findings include: 1. Review of the laboratory's procedures revealed the following policies: Quality Assurance policy (title: Quality Assurance Program) that outlined the Access 2 immunoassay analyzer's calibration verification protocols: "If the test calibration procedures include three or more levels of calibration material (a low, mid, and high value) and is performed at least once every six months, then the requirements for calibration verification are met". Quality Control Policy (title: Quality Control Program) that outlined Access 2 immunoassay's control protocols for Thyroid Uptake: "run BioRad Liquichek Immunoassay Plus Control Level 1 and 3 each day". 2. Review of the Access 2 TU package insert revealed that the reagent included one level of calibrator. 3. Review of the laboratory's Access 2 TU calibration verification records, from August 2019 to the date of the survey on 5/14/21, revealed one calibration verification record performed on 5/13/21. The inspector requested to review additional documentation of TU calibration verification. The lead testing personnel stated: "We performed the verification in the spring of 2019 when we first set up the instrument. We overlooked performing a cal verification for this test analyte in 2020. I recently realized that we had not included it with our other chemistry calibration verifications in 2020 and I ordered a calibrator kit from Audit Micro Controls." 4. In an interview with the primary testing personnel on 5/14/21 at approximately 2:30 PM, the above findings were confirmed.