

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D1029632	<b>(X3) Date Survey Completed</b>  01/24/2025
<b>Name of Provider or Supplier</b>  Virginia Endocrinology & Osteoporosis Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Virginia Endocrinology & Osteoporosis Center on January 23-24, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records and interviews, the laboratory failed to rotate PT among personnel performing Complete Blood Count (CBC) patient testing in one of two years reviewed (2023 and 2024). Findings include: 1. Review of the CMS Form 209 revealed two testing personnel were identified as qualified and responsible for patient CBC testing during calendar years 2023 and 2024 up to the dates of the inspection on 1/23/25-1/24/25. 2. Review of the laboratory's 2024 American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT documentation, a total of three (3) events, revealed that testing personnel A signed attestations for performing: AAB-MLE 2024 Event 1 Hematology Module; AAB-MLE 2024 Event 2 Hematology Module; AAB-MLE 2024 Event 3 Hematology Module; TP A performed 3 of 3 hematology CBC PT events performed in 2024. (See Personnel Code Sheet.) 3. Interviews with the laboratory supervisor on 1/23/25 at 4:00 PM and on 1/24/25 at 11 AM confirmed the above findings.</p>

<p><b>D2009</b></p>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b>  CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:  Based on a review of proficiency testing (PT) documentation, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director and testing personnel for one (1) of six (6) events reviewed. Findings include: 1. Review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT documentation (2023 Events 1-3, 2024 Events 1-3), a total of 6 events, revealed no signed attestation statements for the 2023 Chemistry/Endocrinology and Hematology modules' third event. 2. The inspector requested to review the attestation documentation for the AAB-MLE third event modules listed above. No documentation was available for review. 3. Interviews with the laboratory supervisor on 1/23/25 at 4:00 PM and on 1/24/25 at 11 AM confirmed the above findings.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>  CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:  Based on a review of test logs, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to verify twice annual accuracy of a laboratory-developed test (LDT) for Hemoglobin A1C (HbA1c) from August 2023 to the dates of the inspection January 23-24, 2025. Cross Reference D5407, D5423. Findings include: 1. Review of test logs revealed seven hundred seventy-seven (777) HbA1c tests were resulted utilizing a LDT from 8/11/23 to 1/25/25. 2. Review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT documentation (2023 Events 1-3, 2024 Events 1-3), a total of 6 events, revealed no enrollment in a PT module for the LDT HbA1c test. The inspector requested to review PT or twice annual accuracy verification for the high complexity LDT HbA1c test. No records were available. 3. Interviews with the laboratory supervisor on 1/23/25 at 4:00 PM and on 1/24/25 at 11 AM confirmed the above findings.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b>  CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p>

This CONDITION is not met as evidenced by:  
Based on a review of policies and procedures, observation, manufacturer's operator manual, patient test logs, tour, performance verification documentation, and interviews, the laboratory failed to: 1. document laboratory director approval/review after a modification of the Tosoh G8 HPLC analyzer procedure during seventeen (17) of twenty-two (22) months reviewed - Cross Reference D5407; 2. document evaluation/verification of accuracy, precision, analytical sensitivity, and reportable range for a laboratory developed Hemoglobin A1c test prior to reporting seven hundred seventy-seven patient results from August 2023 to the dates of the inspection January 23-24, 2025 - Cross Reference D5423.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on a review of policies and procedures, observation, manufacturer's operator manual, lack of documentation, and interviews, the laboratory failed to document the laboratory director's (LD) approval/review of a modification of the Tosoh G8 HPLC analyzer procedure for seventeen (17) of twenty-two (22) months reviewed (survey timeframe March 2023 through the dates of inspection January 23-24, 2025). Findings include: 1. Review of the laboratory's policy and procedure manual revealed a procedure for Hemoglobin A1C (HbA1c) testing on the Tosoh G8 HPLC analyzer that was approved by the LD on 8/7/23. The procedure stated under Intended Use: "The Tosoh Automated Glycohemoglobin Analyzer HPLC-723G8 is intended for the in vitro diagnostic use for quantitative measurement of % hemoglobin A1c (HbA1c) in venous whole blood specimens." 2. The inspector observed a nurse deliver a fingerstick sampled tube to the testing personnel and the loading of fingerstick sample onto the Tosoh G8 HPLC analyzer on 1/23/25 at 2 PM. The inspector inquired what sample types were accepted for HbA1c testing on the analyzer. The personnel stated, "We run venous whole blood and fingerstick whole blood samples. A lot of our patients want to know their result while here and it is faster for the nurses to do a fingerstick than to wait for the phlebotomist to draw a tube." 3. Review of the Tosoh G8 Operator's Manual revealed instructions (on page 4) under Section 1.5 Specimen Collection and Handling which stated, "Collect venous whole blood specimens in vacuum collection tubes containing K2-EDTA or K3-EDTA and mix thoroughly. The minimum volume required for analysis directly from collection tubes is 1 mL of whole blood. Venous whole blood samples as small as 50 uL may be used when appropriate sample cup and software options are selected." 4. The inspector requested to review documentation that the LD evaluated/approved/updated the procedure to include fingerstick whole blood sample type (outside of the manufacturer's intended use statement) prior to implementing the laboratory-developed test method in August 2023. The documentation was not provided. 5. Interviews with the laboratory supervisor on 1/23/25 at 4:00 PM and on 1/24/25 at 11 AM confirmed the above findings.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on a tour, review of policy and procedures, observation, manufacturer's user guide instructions, performance verification documentation, patient test logs, and interviews, the laboratory failed to document evaluation/verification of accuracy, precision, analytical sensitivity, and reportable range for their laboratory-developed test (LDT) of Hemoglobin A1c (HbA1c) prior to reporting seven hundred seventy-seven (777) patient results from August 2023 to the dates of the inspection January 23-24, 2025. Findings include: 1. During an entrance tour of the laboratory on 1/23/25 at 1 PM, the inspector noted a new Tosoh G8 endocrinology analyzer in use for HbA1c testing. 2. Review of the laboratory's policy and procedure manual revealed a procedure for HbA1c on the Tosoh G8 HPLC analyzer that was approved by the LD on 8/7/23. The procedure stated under Intended Use: "The Tosoh Automated Glycohemoglobin Analyzer HPLC-723G8 is intended for the in vitro diagnostic use for quantitative measurement of % hemoglobin A1c (HbA1c) in venous whole blood specimens." 3. The inspector observed laboratory testing personnel loading a fingerstick sample on the Tosoh G8 HPLC analyzer on 1/23/25 at 2 PM. 4. Review of the Tosoh G8 Operator's Manual revealed instructions (on page 4) under Section 1.5 Specimen Collection and Handling which stated, "Collect venous whole blood specimens in vacuum collection tubes containing K2-EDTA or K3-EDTA and mix thoroughly." 5. Review of the laboratory's Tosoh instrument verification records revealed the analyzer installation, by a Tosoh field service technical specialist, occurred in August 2023. The inspector noted that the instrument verification of venous whole blood samples was approved by the LD and was placed in use on 8/11/23. The inspector requested to review that performance specifications were established/approved for the LDT fingerstick method. The documentation was not available for review. 6. Review of test logs revealed 14,698 A1c tests were resulted from 8/11/23-1/25/25 on the new Tosoh G8 analyzer -noting that thirteen thousand nine hundred twenty one (13,921) A1c tests resulted from venous blood draw, 777 A1c tests resulted from the LDT fingerstick method. 777 of 14,696 A1c tests were resulted utilizing samples not approved under the manufacturer's intended use from 8/11/23 to 1/25/25. 7. Interviews with the laboratory supervisor on 1/23/25 at 4:00 PM and on 1/24/25 at 11 AM confirmed the above findings.