

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0681032	(X3) Date Survey Completed 10/08/2025
Name of Provider or Supplier Dumfries Health Center	Street Address, City, State 3700 Fettle Park Drive, Dumfries, 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
D0000	An announced CLIA validation survey was conducted at Dumfries Ambulatory Care Center (Dumfries Health Center) on October 7-8, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on an observation, review of the laboratory's policies and procedures, manufacturer's user guide/package inserts, lack of documentation, and interviews, the laboratory failed to follow their established policy to monitor the temperature of stored tests kits to ensure reagents are stored per manufacturer's instructions from January 2024 until September 2025. The findings include: 1. During a tour of the laboratory on October 7, 2025 at 9:10AM, the surveyor observed the following test kits stored in laboratory room 2061: OSOM Infectious Mono Test, Quidel Sofia Influenza A+B FIA, Quidel QickVue Dipstick Strep A, Quidel Sofia RSV FIA, and Beckman Icon 25 hCG Urine and Serum test kits. 2. Review of the laboratory's Quality Management Plan revealed the following statement, "All reagents will be properly stored per manufacturer's instructions." 3. Review of the manufacturer's instructions for use for the test kits stored in room 2061 revealed the following storage</p>

temperature requirements: OSOM Infectious Mono Test: 15-30C Quidel Sofia Influenza A+B FIA: 15-30C Quidel QickVue Dipstick Strep A: 15-30C Quidel Sofia RSV FIA: 15-30C Beckman Icon 25 hCG Urine and Serum: 2-30C 4. Review of the available laboratory records from January 2024 to October 8, 2025 revealed a "Temperature and Humidity" log for room 2061 for September 2025. On October 8, 2025, at 11:00 AM, the surveyor requested to review the temperature logs for room 2061 from January 2024 until September 2025. The laboratory provided no records to review. In an interview with the Technical Supervisor (TS) on October 8, 2025 at 11:00 AM, the TS stated they were not monitoring the temperature of room 2061 prior to September 2025. They stated they were cited by the College of America Pathologists (CAP) inspector and began monitoring the temperature as a result of the inspection. 5. In an exit interview with the TS and Clinic Supervisor on October 8, 2025 at 12:00 PM, the above findings were confirmed.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's Quality Management Plan (QMP), Quality Assurance (QA) documentation, lack of documentation and interviews, the laboratory failed to follow their established QMP to annually review and compare test records to the Genesis Laboratory Information Systems (LIS) records for Estimated Glomerular Filtration Rate (EGFR) for calendar year 2024. The findings include: 1. A review of the laboratory's QMP revealed a statement, "Test records must be reviewed and compared to LIS records on an annual basis to ensure laboratory results are accurately transmitted and transcribed." 2. A review of the laboratory's QA documentation revealed a document, "Verification of Accuracy of Transmission, Calculations and Data Storage/Recovery, Date of Review: 02/14/2025, Frequency: Annual and as needed" with the following statements, "Randomly select a calculated/derived test from the workload and verify the calculations performed by the computer. Record the accession number, the computer results and the manual calculation results on the verification form." 3. In an interview with the Technical Supervisor (TS) on October 8, 2025 at 9:30 AM, the surveyor inquired what test results were calculated by Genesis LIS. The TS stated the calculated results are the Cholesterol/High Density lipoprotein ratio (CHOL/HDL), Low Density Lipoprotein (LDL), Very Low Density Lipoprotein (VLDL) and EGFR. 4. Further review of the QA document, "Verification of Accuracy of Transmission, Calculations and Data Storage/Recovery" revealed a listing of verified calculations for the CHOL/HDL ratio, LDL, and VLDL for calendar year 2024. The surveyor requested to review documentation of the verification of the LIS calculation of the EGFR. The TS stated they did not perform the verification of the calculation of the EGFR in calendar year 2024. They stated they performed the verification in September 2025 after they were cited by the College of American Pathologists' inspector in August 2025 and will perform annually going forward. 5. In an exit interview with the TS and Clinic Supervisor on October 8, 2025 at 12:00 PM, the above findings were confirmed.