Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226649	08/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dominion Medical Associates Inc	304 East Leigh Street - 1st Floor, Richmond, 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 recertification survey was conducted at Dominion Medical Associates, INC August 20-21, 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 laboratory was found to be out of compliance with the following standards and conditions of the CLIA program. CONDITION LEVEL DEFICIENCY found to be out of compliance: D 6000 - 42 CFR 493.1403 Condition: Moderate Complexity Testing Laboratory Director *REPEAT DEFICIENCY.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) and maintenance records, onboard instrument data, and interviews, the laboratory failed to follow their routine workload protocols while analyzing/processing chemistry proficiency testing (PT) challenge samples for one (1) of two (2) PT events in calendar year 2025. Findings include: 1. During a review of QC records for the Horiba Pentra 400 chemistry analyzer for the month of May 2025, the inspector noted that QC was not performed on 5/13/25 and 5 /14/25 for the following analytes: Albumin, Alkaline Phosphatase, Alanine Aminotranserase, Aspartate Aminotransferase, Blood Urea Nitrogen, Calcium, Cholesterol, Chloride, Creatinine, Creatine Kinase, Direct Bilirubin, Glucose, Cholesterol, High Density Lipoprotein, Potassium, Magnesium, Sodium, Total Bilirubin, Total Protein, Triglyceride, and Uric Acid. 2. A review of the Pentra's daily maintenance log for 5/13/25 and 5/14/25 revealed documentation that daily maintenance was performed. 3. The inspector inquired regarding the lack of QC records for the two dates noted and requested to review patient test logs for the dates

	in question. The primary testing personnel (TP) pulled patient data log from the analyzer and it was confirmed that no patient samples were assayed on the dates in question but that proficiency samples for 2025 Event 2 were assayed. The inspector inquired regarding the laboratory's protocol for PT testing within their regular patient workload. The primary TP stated on 8/20/25 at 3:00 PM, "I put all of the patient samples in the refrigerator for those days so that I could focus on running proficiency and getting the results submitted. I always make sure QC is ok before I run patients but did not run QC on the PT testing days." 4. An exit interview with the primary TP on 8/21/25 at 2:00 PM confirmed the above findings.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: A. Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the testing personnel (TP) and laboratory director (LD) for five (5) of five (5) events reviewed for the survey timeframe of October 20, 2023 to August 21, 2025. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records (2024 Events 1-3, 2025 Events 1-2), a total of 5 events, revealed no TP or LD signed attestations for 2024 AAB-MLE Events 1-3 and 2025 AAB-MLE Events 1-2. A total of 5 of 5 chemistry and hematology module events had no attestation statements signed by TP analysts nor LD to document that proficiency testing samples were tested in the same manner as patient specimens. 2. Interviews with the primary TP on 8/20/25 at 4 PM and on 8/21/25 at 2:00 PM confirmed the above finding. B. Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain the AAB-MLE PT program report forms used to record/submit proficiency testing results for four (4) of 5 events reviewed for the survey timeframe of October 20, 2023 to August 21, 2025. Findings include: 1. Review of the laboratory's AAB-MLE PT records (2024 Events 1-3, 2025 Events 1-2), a total of 5 events, revealed no retention of the PT program's packet report forms for 2024 AAB-MLE Events 1-3 and 2025 AAB-MLE Event 1. A total of 4 of 5 chemistry and hematology module records did not include documentation of all steps in the testing /reporting of results for the PT samples (processing the submission of results). 2. Review of the laboratory's 2025 AAB-MLE Event 2 revealed the program's PT instruction sheet with instructions (under heading Reporting Results): "Print the copy that appears on the screen after clicking submit. This copy will include your submission confirmation number. Keep the submission forms in your records." 3. The inspector inquired of the laboratory's policy related to maintaining PT records, including the report forms used to record/submit results. The primary TP stated on 8 /20/25 at 1 PM, "I was not aware that we were to save all of the PT booklet records. I did start with that last event because they had reported one of our results incorrectly before and we did not have a record to show that we actually submitted it correctly.

	When I called them, they told me that I should keep the packet and report forms with the PT records." 4. An exit interview with the primary TP on 8/21/25 at 2:00 PM confirmed the above findings.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of manufacturer's instructions, and interview, the laboratory failed to follow manufacturer's instructions for the one (1) of 1 personnel safety station's eyewash solution as observed during the dates of inspection, August 20-21, 2025. Findings include: 1. During a tour of the laboratory on 8/20/25 at 10 AM, the inspector noted a Honeywell wall emergency eyewash station in use on the hematology bench. The station consisted of one bottle of saline eye wash reagent (Lot F19050-21). The inspector noted that the reagent had a manufacturer's expiration stamped date of 02/2022. 2. Review of the manufacturer's instructions revealed instructions, "Ensure the eyewash bottle is within its shelf life and not expired. Always check the expiration date printed on the bottle. Expired solution can become stagnant and harbor bacteria, which can lead to serious eye infections." 3. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on review of chemistry analyzer's maintenance records, lack of documentation, and interviews, the laboratory failed to document Horiba Pentra 400 monthly preventative maintenance procedures according to manufacturer's protocol for two (2) of twelve (12) months in calendar year 2024. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's Pentra 400 chemistry monthly maintenance logs revealed instructions to record the following monthly preventative maintenance tasks: Wash/Cleaning Procedure, Syringe Plunger Tip Replacement, Check Glycol level, and Perform Qualitest (CV less than 1%). The inspector noted the above four monthly tasks were not documented as performed in October and June of calendar year 2024. The inspector requested to review records for the performance of the monthly maintenance. No additional records were available for review. 2. Review of the laboratory's monthly Quality Assurance (QA) Corrective Action logs for the 2 months outlined above revealed no record of corrective action for the missed Pentra monthly maintenance procedures. 3. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings. B. Based on review of chemistry analyzer's maintenance records, lack of documentation, manufacturer's user guide, and interviews, the laboratory failed to document Horiba Pentra 400 bi-monthly preventative maintenance according to manufacturer's instructions during

	twenty-two (22) of 22 months of survey timeframe (October 20, 2023 to August 20-21, 2025). Findings include: 1. Review of the laboratory's Horiba Pentra 400 chemistry monthly maintenance logs from October 2023 through August 20, 2024 revealed "Filter Replacement" was denoted as to be performed bimonthly. The inspector noted that the bimonthly maintenance was not documented on the Pentra monthly logs during the 22 months reviewed. The inspector requested to review records for the performance of the bimonthly maintenance. No additional records were available for review. The primary testing personnel (TP) stated on 8/21/25 at 1 PM, "Our field service rep performed that for us but I do not have the records." 2. Review of the Pentra 400 users guide revealed instructions under Section: Maintenance and Troubleshooting -"The filter replacement procedure should be performed on a bimonthly basis (every two months)." 3. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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. This STANDARD is not met as evidenced by: Based on a review of manufacturer's package inserts, calibration verification records, and interview, the laboratory failed to document a review and interpretation/approval for chemistry test analytes' six month linearity verification studies according to the manufacturer's instructions for three (3) of 3 linearity events reviewed for calendar year 2024 and year to date 2025. Findings include: 1. Review of the Horiba Pentra 400 general calibrator package insert revealed instructions that stated "linearity studies are performed twice yearly (every 6 months to verify calibration) for all assays utilizing the one point multi-chem calibrator and for the two point HDL calibrator". 2. Review of the laboratory's 2024 and 2025 Pentra chemistry analyzer calibration records revealed documentation of calibration verification with Audit Micro Control calibration materials was performed and submitted in June and December of 2024, and June 2025 for the following analytes: Albumin, Alkaline Phosphatase, Alanine Aminotranserase, Aspartate Aminotransferase, Blood Urea Nitrogen, Calcium, Cholesterol, Chloride, Creatinine, Creatine Kinase, Direct Bilirubin, Glucose, Cholesterol, High Density Lipoprotein, Potassium, Magnesium, Sodium, Total Bilirubin, Total Protein, Triglyceride, and Uric Acid. 3. The inspector noted that the Linearity/Calibration Verification Reports' approval signature line for the twenty-one

	analytes outlined above were left unsigned. The Audit MicroControl manufacturer report provided a signature line and date line which included statement, "Audit MicroControls, Inc. assumes no responsibility for the reading and interpretation of the data. Review and acceptability should be completed based on methodology, clinical significance and laboratory director decision. Each laboratory is responsible for establishing if acceptable". The inspector requested to review documentation that the calibration verification reports were reviewed and approved by the laboratory director. No documentation was available for review. 4. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (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 a tour, review of procedures, manufacturer's instructions, daily temperature and quality assessment (QA) logs, lack of documentation, and interviews, the laboratory failed to outline correct criteria for proper storage of blood collection tubes and chemistry reagents, and failed to document corrective action on dates that the storage room temperature was outside of manufacturer's criteria on one hundred seventy-two (172) of four hundred twenty-five (425) days during the twenty-two month review timeframe (October 20, 2023 to the first day of the inspection on August 20, 2025). **REPEAT DEFICIENCY Findings include: 1. During a tour of the laboratory on 8/20/25 at 10 AM, the inspector noted an AcuRite digital thermometer located on the chemistry work bench recording 79 degrees Fahrenheit (F) /26 Celsius (C). The inspector also noted a Tosoh A1A chemistry immunoassay analyzer in use with substrate, diluent, and wash solutions assaying patient samples for Vitamin D, Prostate Specific Antigen, Free Thyroxine, Thyroid Stimulating Hormone, Vitamin B12, and C-Peptide. The inspector noted one thousand two-hundred twenty-five (1,225) Becton Dickinson (BD) Vacutainer Blood Collection Tubes were stored in laboratory: Buffered Sodium Citrate (2 boxes of 100 tubes, one opened box of 25 tubes), K2 EDTA (5 boxes of 100 tubes), Serum Separator Tubes (SST) 3.5 mL (2 boxes of 100 tubes), and SST 8.5 mL (3 boxes 100 tubes). 2. Review of Tosoh AIA chemistry protocols revealed instructions that stated under Storage and Stability instructions, "Substrate solution is stable opened at 18-25 C. Working diluent and wash solutions are stable 30 days at room temperature 18-25 C." 3. Review of the BD Vacutainer blood collection tubes' manufacturer labels on the stored tubes (outlined above) revealed stamped temperature storage limitations as 4-25 C. Review of BD manufacturer's online package insert for the vacutainer types outlined above revealed instructions, "The storage temperature range is 4-25 C (39-77 F). Storing vacutainer tubes within the limitations is important for vacuum integrity. High temperatures can negatively impact the vacuum seal potentially leading to insufficient blood collection and inaccurate results. The chemical additives in the vacutainer tubes are crucial for preserving blood samples can be affected by high temperatures, compromising effectiveness and lead to inaccurate results." 4. Review of the daily temperature logs during the review timeframe of 10/20/23 - 8/20/25 revealed that the laboratory's recorded/monitored room temperature exceeded the upper limit of the storage criteria (25 C) for the Tosoh reagents and BD Vacutainer tubes outlined above on the following 142 days: 2/27/24, 4/11/24, 4/18-4/19/24, 4/29-4/30/24, 5/1/24, 5/21-5/24/24, 5/29/24, 5/31/24, 6/4-6/5/24, 6/10-6/14/24, 6/17-6/21/24, 6/24-6/28/24, 7/15-

	7/19/24, 7/22-7/26/24, 7/29-7/31/24, 8/1-8/2/24, 8/5-8/9/24, 8/12-8/16/24, 8/19-8/23 /24, 8/26-8/30/24, 9/3-9/4/24, 9/25-9/27/24, 9/30/24, 10/1-10/4/24, 10/7-10/11/24, 10 /14-10/18/24, 10/21-10/25/24, 10/29-10/30/24, 11/7/24, 12/5/24, 12/9-12/13/24, 12/23 /24, 12/27/24,12/30-12/31/24, 2/25-2/28/25, 4/14-4/15/25, 4/21-4/22/25, 4/25/25, 4/28-4/29/25, 5/2/25, 5/5-5/6/25, 5/9/25, 5/12-5/16/25, 5/19-5/20/25, 6/4/25, 6/6/25, 6/9-6 /13/25, 6/16-6/20/25, 6/23-6/27/25, 7/1-7/2/25, 7/7-7/11/25, 7/14-7/18/25, 7/21-7/25 /25, 7/28-7/31/25, 8/6/25, 8/8/25, 8/11-8/15/25, 8/18-8/20/25. 5. The inspector noted that the room temperature logs stated acceptable range as 18-30 C. The inspector inquired of the primary testing personnel (TP) regarding the criteria for the upper limit exceeding BD Vacutainer and Tosoh reagent storage temperature limit of 25 C. The primary TP stated on 8/20/25 at 2 PM, "We can modify our temperature charts to meet those requirements and I will speak with the lab director about checking our air conditioning. We do have days that get very hot in the lab when the instruments are running especially in the summer months." 6. Review of monthly QA corrective action logs for the timeframes outlined above revealed no record of corrective action for the dates when temperatures exceeded upper limits for storage criteria of Tosoh substrate, diluent, and wash reagent and for the vacutainer blood collection tubes stored for patient chemistry and hematology analysis. 7. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) monthly statistical reports, policies, lack of documentation, and interviews, the laboratory failed to follow their policy to document monthly hematology, chemistry/endocrinology QC statistical review and failed to identify the lapse in review during twenty-two (22) of 22 months surveyed (timeframe: October 20, 2023 through date of inspection on August 20-21, 2025). Findings include: 1. A review of the monthly Medonic hematology QC files revealed that the monthly Levey Jennings (LJ) statistical reports for the Complete Blood Count parameters (White Blood Count, Red Blood Cell Count, Hemoglobin, Hematocrit, MCV, MCH, and Platelets) were not evaluated/reviewed during the 22 month timeframe (October 2023 through the dates of the inspection August 20-21, 2025). 2. A review of the monthly Horiba Pentra 400 chemistry QC files revealed that the monthly LJ statistical reports for the following analytes were not evaluated/reviewed during the 22 month timeframe outlined above: Albumin, Alkaline Phosphatase, Alanine Aminotranserase, Aspartate Aminotransferase, Blood Urea Nitrogen, Calcium, Cholesterol, Chloride, Creatinine, Creatine Kinase, Direct Bilirubin, Glucose, Cholesterol, High Density Lipoprotein, Potassium, Magnesium, Sodium, Total Bilirubin, Total Protein, Triglyceride, and Uric Acid. 3. A review of the monthly Tosoh A1A 2000 ST chemistry QC files revealed that the monthly LJ statistical reports for the following analytes were not evaluated/reviewed for the 22 month timeframe outlined above: C-Peptide, Prostate Specific Antigen, Thyroid Stimulating Hormone, Thyroxine Free T4, Vitamin B12, and 25-OH Vitamin D. 4. The inspector requested documentation that analytes assayed on the Medonic, Pentra, and Tosoh LJ statistics were reviewed/evaluated during the 22 months of review. No documentation was available. 5. Review of the laboratory's policies revealed a quality assurance

	(QA) plan that included a monthly checklist. The inspector noted that the checklist included a guideline for hematology and chemistry analyzers' LJ reports which stated, "QC reports will be printed by the 5th of each month for all moderate complexity analyzers. The charts will be reviewed and signed by the lab director monthly." The inspector inquired regarding corrective action records for the lapses in monthly QC review. No corrective documentation records were available. 6. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings.
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 a tour, review of procedures, manufacturer's instructions and package inserts, calibration verification records, daily temperature and quality assessment logs, chemistry analyzer's maintenance records, manufacturer's user guide, quality control monthly statistical reports, lack of documentation, and interviews, the laboratory director failed to provide overall management and direction to assure the quality of laboratory services were provided during the survey timeframe of October 20, 2023 to August 21, 2025 **REPEAT DEFICIENCY (Refer to D6020 and D6023).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a tour, review of procedures, manufacturer's instructions, daily temperature and quality assessment logs, chemistry analyzer's maintenance records, manufacturer's user guide, lack of documentation, and interviews, the laboratory director failed to: 1. ensure that correct temperature criteria was established for monitoring proper storage of blood collection tubes and chemistry reagents and failed to ensure that corrective action was tasked on dates that the storage room temperature was outside of manufacturer's criteria on one hundred seventy-two of four hundred twenty-five days during the twenty-two month review timeframe of October 20, 2023 to the first day of the inspection on August 20, 2025 (Refer to D5785 **REPEAT DEFICIENCY); 2. ensure that the laboratory performed Horiba Pentra 400 monthly and bimonthly preventative maintenance according to manufacturer's protocols and failed ensure corrective action was tasked for missed maintenance during the twenty-two months timeframe 10/20/23 to 8/20/25 (Refer to D5429 **REPEAT DEFICIENCY).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

	This STANDARD is not met as evidenced by: Based on a review of manufacturer's package inserts, calibration verification records, quality control (QC) monthly statistical reports, policies, lack of documentation, and interviews, the laboratory director failed to: 1. document review and interpretation /approval for chemistry analytes' six month linearity verification studies according to the manufacturer's instructions for three (3) of 3 linearity events reviewed in 2024 and year to date 2025 (Refer to D5439); 2. ensure that monthly hematology, chemistry /endocrinology QC statistical review was performed per policy and failed to identify the lapse in review during twenty-two (22) of 22 months reviewed (Refer to D5791).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interview, the technical consultant (TC) failed to document semiannual competency assessments for one (1) of two (2) testing personnel (TP) during the review timeframe of October 20, 2023 to the inspection August 20-21, 2025. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) also serves in the role of TC. The CMS 209 listed 2 TP as responsible for performing non-waived hematology, chemistry, and endocrinology patient testing on Medonic M Series, Tosoh A1A 2000 ST, and Horiba Pentra 400 analyzers during the review timeframe (10/20/23-8/21/25). 2. Review of personnel records revealed that TP A's initial training on Medonic hematology, Tosoh A1A and Horiba Pentra chemistry/endocrinology analyzers was recorded in September-October 2023. TP A's files lacked semiannual hematology/chemistry/endocrinology competency assessments (*See Personnel Code Sheet). 3. The inspector requested to review documentation that competency assessments were performed twice during TP A's first year of testing. The additional documentation was not available. The inspector noted a general laboratory annual competency was completed and signed by the LD on 4/4 /25. The inspector inquired regarding the laboratory's policy for testing personnel training and competency assessment. No policy was available for review. 4. An exit interview with the primary testing personnel on 8/21/25 at 2:00 PM confirmed the above findings.