Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226649	10/19/2023
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 on October 18 and 19, 2023 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, including the Conditions under 42 CFR part 493 CLIA Regulations: D6000 - 42 CFR. 493.1403 Condition: Moderate Complexity Laboratory Director; D6063 - 42 CFR. 493.1421 Condition: Laboratory Testing Personnel.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, lack of documentation, and interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) for three (3) of five (5) events during the twenty-one months reviewed (January 2022 to October 18-19, 2023). **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's PT records revealed: 2022 Medical Laboratory Evaluation (MLE) documentation, a total of 3 events (M1-M3), had no signed LD attestation statements for M2 or M3; 2023 American Association of

	Bioanalysts Medical Laboratory Evaluation (AAB-MLE) documentation, total of two events (M1-M2), had no signed LD or designee attestation for M2. A total of 3 of the 5 PT events had no attestation statements signed by the LD. 2. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above finding.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, review of daily temperature logs, lack of documentation, Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), and an interview, the laboratory failed to monitor the main laboratory freezer during six (6) of twelve (12) months in calendar year 2022. Findings include: 1. During a tour of the laboratory on 10/18/23 at 11 AM, the inspector observed a freezer in use for storage of patient samples for reference laboratory courier pick up. 2. Review of temperature logs from January 2022 and up to the date of survey on 10 /18/23 revealed no documentation that the laboratory freezer temperatures were recorded for the following 6 months in calendar year 2022: July, August, September, October, November, December. The inspector requested to review the temperature logs for the 6 months outlined above. No additional records were available for review. 3. Review of CMS-2567 POC protocol (LD signed/approved 11/13/19) revealed a corrective action plan for monitoring the laboratory freezer that stated "The laboratory director has assigned the primary testing personnel to monitor and chart daily laboratory freezer 0 to -15 degrees Celsius." 4. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above findings.
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: A. Based on review of monthly maintenance records, lack of documentation, and interview, the laboratory failed to document Tosoh A1A chemistry immunoassay analyzer's weekly preventative maintenance according to manufacturer log protocols in five (5) of twelve (12) weeks reviewed in the months of November 2022, December 2022, and January 2023 (survey review timeframe: January 2022 to the date of the inspection October 18, 2023). Findings include: 1. Review of the laboratory's Tosoh A1A monthly maintenance logs revealed instructions to record the following two weekly maintenance tasks: Clean B/F Wash Probe Tip, Clean Substrate Line with 70 % Ethanol (5 times). The inspector noted that the above two

	maintenance tasks were not documented weekly while the instrument was in use in the following three (3) months (survey review timeframe: January 2022 to 10/18/23): November 2022 -one of four weeks missed documentation; December 2022 -one of four week missed documentation; January 2023- three of four weeks missed documentation. 5 of 12 weeks lacked documentation of weekly cleaning protocols during the 3 months outlined above. 2. Review of monthly Quality Assurance (QA) corrective action logs for the 3 months outlined above revealed no record of corrective action for the missed Tosoh cleaning maintenance procedures. 3. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above findings. B. Based on review of monthly maintenance records, lack of documentation, and interview, the laboratory failed to document Horiba Pentra 400 Chemistry analyzer's weekly preventative maintenance according to manufacturer log protocols in eight (8) of 8 weeks during the months of June and December 2022 (survey review timeframe: January 2022 to the date of the inspection October 18, 2023). 1. Review of the laboratory's Horiba Pentra chemistry monthly maintenance logs revealed instructions to record the following two weekly maintenance tasks: ISE module cleaning with depro, Perform Needle Depro with Mixer. The inspector noted the above two maintenance tasks were not documented weekly while the instrument was in use during the following two (2) months (survey timeframe: January 2022 to 10/18/23): June 2022 -four of four weeks missed documentation; December 2022 -four of four week missed documentation. 8 of 8 weeks lacked weekly preventative maintenance documentation in the 2 months outlined above. 2. Review of monthly Quality Assurance (QA) corrective action logs for the 2 months outlined above revealed no record of corrective action for the missed Pentra cleaning maintenance procedures. 3. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above findings.
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 a tour, review of procedures, daily temperature and quality assessment (QA) logs, lack of documentation, and an interview, the laboratory failed to document corrective action on dates that the room temperature was outside of manufacturer's criteria on thirty-eight (38) of four hundred twenty (420) days during a twenty-one month review timeframe (January 2022 to the first day of the inspection on October 18, 2023). Findings include: 1. During a tour of the laboratory on 10/18/23 at 11 AM, the inspector noted a Tosoh A1A chemistry immunoassay analyzer in use to assay patient samples for Vitamin D, Prostate Specific Antigen, Free Thyroxine, Thyroid Stimulating Hormone, Vitamin B12, and C-Peptide. The inspector also noted the laboratory room temperature reading on the Streck counter thermometer as 80.6 degrees Fahrenheit (27 degrees Celsius {C}). 2. Review of the laboratory's procedure manual revealed a Tosoh AIA chemistry procedure 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 daily temperature logs from January 2022 to the first date of the survey on 10/18/23 revealed that the laboratory's recorded room temperature exceeded the above Tosoh reagent storage protocol criteria (18-25 C) on the following 38 days: 5/20/22, 6/10/22,

	6/15/22, 6/16/22, 6/30/22, 7/8/22, 7/15/22, 7/18/22, 7/23/22, 7/25/23, 8/7/22, 9/18/22, 10/7/22, 10/21/22, 11/18/22, 4/19/23, 5/19/23, 5/24/23, 5/31/23, 6/7/23, 6/12/23, 6/13 /23, 6/16/23, 6/19/23, 7/6/23, 7/12/23, 7/14/23, 7/18/23, 7/20/23, 7/26/23, 7/27/23, 8/2 /23, 8/4/23, 8/8/23, 8/15/23, 8/17/23, 8/22/23, 8/29/23. 4. Review of monthly QA corrective action logs for the timeframes outlined above revealed no record of corrective action for temperatures that exceeded the proper storage criteria for Tosoh substrate, diluent, and wash reagent storage. 5. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above finding.
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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) records, quality control and test logs, and interview, the laboratory director (LD) failed to: document training for one new TP before allowing the testing of patient hematology samples from May 2023 to the date of the inspection, October 18-19, 2023 (See D6029); and outline, in writing, the non-waived hematology patient testing duties/procedures for one of three TP from May 2023 to the date of the inspection, October 18-19, 2023 (See D6032).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of test logs, personnel training records, and interview, the laboratory director failed to document training for one (1) new testing personnel (TP) before allowing the testing of patient hematology Complete Blood Count (CBC) samples from May 2023 to the date of the inspection, October 18-19, 2023. Findings include: 1. Review of patient test logs revealed that TP A began operating/reporting CBC patient testing and analyzer quality control samples in May 2023 on the Medonic Hematology analyzer. *See attached Personnel Code Sheet. 2. Review of laboratory TP files revealed no documentation of an initial hematology training for TP A. 3. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) records, quality control and test logs, lack of documentation, and interview, the laboratory director (LD) failed to outline, in writing, the non-waived hematology patient testing duties/procedures for one of three (3) TP from May 2023 to the date of the inspection, October 18-19, 2023. Findings include: 1. Review of the CMS 209 form with the lead laboratory technologist on 10/18/23 revealed that the LD identified 3 TP as qualified/responsible for non-waived chemistry and hematology patient testing. TP A was identified as a new hire that started testing in spring 2023. The inspector inquired regarding the date of initial training for TP A. No information was provided regarding the start date for TP A. *See Personnel Code Sheet. 2. Review of the laboratory's Medonic hematology analyzer's QC and patient test records revealed TP A was documented as a hematology testing operator as of May 2023. 3. Review of the available TP records revealed no hematology procedure performance job description, training, or competency assessment outlined for TP A. No additional records were available for review at request. 4. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, available testing personnel records, patient test logs, and interview, the laboratory failed to retain documentation of personnel qualifications for one of three testing personnel from May 2023 to the date of the survey October 18-19, 2023. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a

	chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), available testing personnel (TP) records, test logs, and interview, the laboratory failed to retain documentation of personnel qualifications for one of three (3) TP responsible for reporting patient hematology test results from May 2023 to the date of the inspection October 18-19, 2023. Findings include: 1. Review of the laboratory's CMS 209 form revealed 3 TP identified as qualified to perform non-waived hematology Complete Blood Count (CBC) patient testing. 2. Review of personnel documents revealed no education documentation for TP A. *See Personnel Code Sheet. The inspector noted American Heart Association Cardiopulmonary Resuscitation, National Healthcare Association Phlebotomy /Medical Assistant/EKG Technician training certificates in TP A's personnel file. The inspector requested to review TP A's qualifications such as education diploma or official transcript. No additional education documents were provided. 3. Review of 2023 Medonics Hematology Analyzer Quality Control (QC) logs and patient test records revealed TP A as a hematology testing operator reporting non-waived CBC results starting in May 2023. 4. An interview with the practice manager on 10/19/23 at 2 PM confirmed the above findings