Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226649	12/08/2021
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 on 12/08/21 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D6000 - 42 C.F. R. 493-1403 Condition: Laboratory Director (Moderate Complexity).
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation and interviews, the testing personnel (TP) failed to sign three of the five attestation statements reviewed. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) hematology PT records for third event in 2019 and all three events in 2020 and the first event in 2021 revealed lack of the TP signature of the attestation statements for the following: 2020 MLE M2- no signature by the TP, 2020 MLE M3- no signature by the TP and 2021 MLE M1- no signature by the TP. 2. Interview with the primary TP on 12/08/21 at approximately 2:00 PM confirmed the findings. An exit interview with the lab director on 12/08/21 at approximately 2:20 PM confirmed the findings.
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 the review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to maintain documentation of the attestation statement for two of seven events reviewed. Findings include: 1. Review of the available Medical Laboratory Evaluation (MLE) PT records revealed lack of documentation of the attestation statement for the 2021 MLE M2 and MLE M3 events. 2. Interview with the primary TP on 12/08/21 at approximately 2:00 PM confirmed the findings. An exit interview with the lab director on 12/08/21 at approximately 2:20 PM confirmed the findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on a review of quality control (QC) records, lack of documentation, and interviews, the laboratory failed to retain the "Boule Quality Control " manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for seven of eight lot numbers utilized from 06/01 /20 and up to 12/08/21. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts and daily QC records from 06/01/20 and up to 12/08/21 revealed the laboratory received and utilized eight lot numbers of the "Boule QC" to perform daily QC procedures for the CBC testing. The following seven QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: 22005-31, 22008-21, 22101-31, 22104-01, 22105-31, 22106-31, and 22017-31. 2. Interview with the primary TP on 12/08/21 at approximately 2:00 PM confirmed the findings. An exit interview with the lab director on 12/08/21 at approximately 2:20 PM confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for

	the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's performance verification records, and an interview, the laboratory failed to verify the reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the Medonic M-Series hematology analyzer prior to reporting patient results on 05/26/21 and up to the date of survey on 12/13/21. Findings include: 1. Review of the laboratory's Medonic M-Series (serial number 48779, installed 05/26/21) hematology analyzer's performance verification documentation revealed the documentation did not include verification of the reference (normal) ranges for CBCs after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reference (normal) ranges. The laboratory provided no documentation for review. 2. Interview with the primary TP on 12/08/21 at approximately 2:00 PM confirmed the findings. An exit interview with the lab director on 12/08/21 at approximately 2:20 PM confirmed the findings. B. Based on review of the laboratory's performance verification records, and interviews, the laboratory failed to verify the reference (normal) ranges for six immunoassays performed on the Tosoh AIA 2000 analyzer prior to reporting patient results on 12/19/19 and up to the date of survey on 12/13/21. Findings include: 1. Review of the laboratory's Tosoh AIA 2000 (serial number 10638212, installed 12/13/19) immunoassay analyzer's performance verification documentation revealed the documentation did not include verification of the reference (normal) ranges for C-Peptide (C-P), Free Thyroxine (FT4), Vitamin D 25 OH (Vit D), Vitamin B12 (Vit B12), Prostate Specific Antigen (PSA), and Thyroid Stimulating Hormone (TSH) analytes after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reference (normal) ranges. The laboratory provided no documentation for review. 2. Interview with the primary TP on 12/08/21 at approximately 2:00 PM confirmed the findings. An exit interview with the lab director on 12/08/21 at approximately 2:20 PM confirmed the 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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records and interviews, the laboratory director failed to ensure that one of one new TP had documented training and competency assessments prior to performing patient testing procedures for hematology (Refer to D6029). REPEAT DEFICIENCY.
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: **REPEAT DEFICIENCY** Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records and interviews, the laboratory director failed to ensure that one of one new TP had documented training and competency assessments prior to performing patient testing procedures for hematology at the date of survey on 12/08/21. Findings include: 1. Review of CLIA CMS-209 form revealed TP A listed as performing patient testing. (See attached TP Code Sheet). 2. Review of TP records and an interview with TP A on 12 /08/21 at approximately 1:30 PM revealed that TP A was hired sometime after the install of the new hematology analzyer on 05/26/21. They stated "I have been testing CBCs for a few months." The inspector requested to review training and competency assessments performed for TP A. The documentation was not available for review. 3. Interview with the primary TP on 12/08/21 at approximately 2:00 PM confirmed the findings. An exit interview with the lab director on 12/08/21 at approximately 2:20 PM confirmed the findings.