| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 49D0226649 | 09/12/2019 |
| **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 |
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| **D0000** | An announced CLIA recertification survey was conducted at Dominion Medical Associates, INC on September 11 and 12, 2019 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: |
| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.<br><br>This CONDITION is not met as evidenced by:<br>Based on a laboratory tour and interviews with the primary testing personnel and laboratory director, the laboratory's work environment failed to: 1. provide adequate space to safely conduct pre-analytical, analytical, and post-analytical phases of non-waived hematology and chemistry testing. (See D3001.) 2. ensure minimized contamination of the patient phlebotomy draw station, instrument reagent/supply items, chemistry and hematology analyzer(s) at the time of the survey on September 11 and 12, 2019. (See D3003.) |
| **D3001** | FACILITIES<br>CFR(s): 493.1101(a)(1) |

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| | The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory tour observations and interviews, the laboratory room environment failed to provide adequate space to safely conduct pre-analytical, analytical, and post-analytical phases of non-waived hematology and chemistry testing. Findings include: 1. During a tour of the laboratory on September 11, 2019 at approximately 10:00 AM, the inspector observed and noted: - two (2) open biohazard waste bins and a large waste can on the floor directly in front of the Horiba Pentra 400 chemistry analyzer bench blocking access to the instrument; - three (3) large cardboard boxes of laboratory supplies and a black canvas luggage type bag (filled with hematology packing slips and instrument print outs) blocking access to the Medonic M Series hematology analyzer bench; - a tube rack holding thirty (30) patient serum samples tipped over behind a box sitting on the hematology workbench; - 3 chairs in the walkway between the laboratory entrance, hematology bench, and the phlebotomy draw chair which was located inside the chemistry testing area; - one (1) rack of twenty-four (24) patient serum tubes and an open biohazard container sitting on top of the Tosoh A1A 900 immunoassay chemistry analyzer (utilized as a bench work area); - a male patient sitting in the phlebotomy chair (adjacent to the Tosoh A1A 900 chemistry immunoassay analyzer) in close proximity (approximately five inches) to a rack of 24 patient serum samples and immunoassay chemical reagents in preparation for an assay; six (6) observations of limitations of space on bench work area and floor plan that prevented safe movement to conduct laboratory testing. The inspector also observed, during the tour at approximately 10:30 AM, the primary testing personnel (TP) tripped on one of the 3 chairs in the testing area while walking to place samples on the hematology rocker (which was on top of the Medonic analyzer). The inspector reached out to assist the TP from falling. The primary TP stated, "I wish we had more space. Please watch your step." 2. In an interview with the laboratory director and primary TP at approximately 12:30 PM on 9/12/19, the above findings were confirmed. The laboratory director stated, "I have noted the limited walking space in the lab room and have had conversations with the staff that it is an area that needs improvement". |
| **D3003** | FACILITIES<br>CFR(s): 493.1101(a)(2)<br><br>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.<br><br>This STANDARD is not met as evidenced by:<br>Based on tour observations and interviews, the laboratory's organization, arrangement, and utilization of bench top and floor space failed to ensure minimized contamination of the patient phlebotomy draw station, instrument reagent/supply items, chemistry and hematology analyzer(s) at the time of the survey on September 11 and 12, 2019. Findings include: 1. During a tour of the laboratory on September 11, 2019 at approximately 10:00 AM, the inspector noted: - dried blood and reagent residue stains on the outer cabinet of the Horiba Pentra 400 chemistry analyzer; - three (3) large cardboard boxes of laboratory supplies and a black canvas luggage type bag (filled with hematology packing slips and instrument print outs) on the floor in front of the |

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| | Medonic M Series hematology analyzer bench; - a patient sitting in the phlebotomy draw chair (which was located inside the chemistry testing area adjacent to the Tosoh A1A 900 analyzer) within close proximity of a biohazard waste container atop of an analyzer, reagent chemical preparations, and a tube rack of twenty-four (24) blood samples. The above observations were noted as indicators that utilization of bench top and floor space failed to ensure minimized contamination for patients, testing personnel, equipment, and supplies (stored on the floor obstructing access to instrumentation). The inspector also noted, at approximately 10:30 AM, primary testing personnel (TP) tripped, almost falling on one of the 3 chairs in the testing area, while walking with blood samples towards the hematology rocker device (which was atop of the Medonic analyzer).The inspector made record of the observation as the potential dropping of a patient specimen could result in the specimen leaking and contaminating the surfaces it comes in contact with and the patient phlebotomy draw station. 2. In an interview with the laboratory director and primary TP at approximately 12:30 PM on 9/12/19, the above findings were confirmed. The laboratory director stated, "I have noted the limited walking space in the lab room and have had conversations with the staff that it is an area that needs improvement". |
| **D5201** | CONFIDENTIALITY OF PATIENT INFORMATION<br>CFR(s): 493.1231<br><br>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory tours and interviews, the laboratory failed to ensure confidentiality of patient information due to placement of their phlebotomy draw station adjacent to the chemistry immunoassay testing area during the twenty-four (24) of 24 months reviewed. Findings include: 1. During a laboratory tour on 9/11/19, at approximately 10:30 AM, the inspector noted a male patient sitting in the phlebotomy chair (adjacent to the Tosoh A1A 900 chemistry immunoassay analyzer) in close proximity (approximately 5 inches) to where a rack of twenty-four (24) patient serum samples were sitting atop of the Tosoh instrument. The inspector noted that the patient names and tests ordered were visible on the barcoded specimen tubes to the blood draw station chair. The inspector inquired as to a description of the typical specimen loading process for the Tosoh 900. The primary testing personnel (TP) stated, "I am the full time testing person in our lab and I run the samples for the Tosoh. I get all the calibrations and controls that are required loaded and then sort and place the samples for each day's run." The inspector asked what work space was utilized for the work described during the timeframe of August 2017 to the date of the survey. The primary TP stated, "I have used the area on top of the 900 to set up the runs for that all of that time. We do not have extra bench top on this side". 2. On 9/12 /19 at approximately 9:30 AM, the inspector inquired how long the patient phlebotomy blood draw station had been located inside the laboratory testing area. The primary TP stated, "We have had them come into the lab for many years, but it would be better if we could use a patient exam room for blood draws rather than into the lab area so close to all of the instruments and samples." 3. In an interview with the laboratory director and primary TP at approximately 12:30 PM on 9/12/19, the above findings were confirmed. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250 |

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| | 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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a tour, review of procedures, manufacturer's guidelines, daily temperature /relative humidity (RH%) logs, calibration records, and an interview, the laboratory failed to: 1. ensure that the Vitamin D, 25 OH chemistry procedure included and followed manufacturer's guidelines for patient specimen collection, storage preservation, and rejection criteria for assays during twenty-four (24) of 24 months reviewed. Timeframe: September 2017 to the date of the survey September 12, 2019. (See D5403); 2. ensure manufacturer's environmental operating requirements were maintained for two chemistry analyzers during 24 of 24 months reviewed. (See D5413 A); 3. monitor the AGEIS Scientific refrigerator to ensure the storage temperature was within Tosoh manufacturer's acceptable range of 2- 8 degrees Celsius for C-Peptide (C-P), Free Thyroxine (FT4), Prostate Specific Antigen (PSA), and Thyroid Stimulating Hormone (TSH) reagents from January 2019 to the date of the survey on September 12, 2019. (See D5413 B); 4. document Tosoh A1A 900 calibration procedures for PSA according to the every ninety (90) day frequency recommended by the manufacturer from 1/2/19 to 5/27/19. (See D5437). |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on a tour, review of procedures, and interviews, the laboratory's Vitamin D, 25 OH (Vit D) chemistry procedure failed to include guidelines for patient specimen collection, storage preservation, or rejection criteria for patient assays during twenty-four (24) of 24 months reviewed. Findings include: 1. During a tour of the laboratory |

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| | on 9/12/19 at approximately 9:00 AM, the inspector noted a rack of patient specimens (approximately twenty-four tubes) that appeared to have tipped over behind a box, beside the Medonic M Series hematology analyzer, with barcoded test labels identifying Vit D as ordered testing. The patient samples' labels identified the dates of collection as ranging from 9/6/19 to 9/10/19. The inspector inquired regarding the position of the rack and the timeframe after collection for assaying the samples. The primary testing personnel stated, "We do not have enough space to sit our chemistry racks over in chemistry, so the samples were put over there until I can get them on the instrument". 2. Review of the laboratory procedure manual revealed an approved procedure for Vit D on the the Tosoh immunoassay chemistry analyzer. The procedures were approved by the laboratory director annually in 2018 and 2019. The inspector noted that the procedure lacked instructions for patient specimen collection, guidelines for storage preservation, and rejection criteria. The inspector requested to review the procedure criteria outlined above. The inspector specifically requested to view the laboratory's protocol for specimen storage when Vit D patient assays are performed beyond twenty-four (24) hours of collection. The documentation was not available for review. 3. In an interview with the laboratory director and primary testing personnel at approximately 12:30 PM on 9/12/19, the above findings were confirmed |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on a tour, review of manufacturer's guidelines, daily temperature/relative humidity (RH%) logs, and an interview, the laboratory failed to ensure manufacturer's environmental operating requirements were followed for two (2) chemistry analyzers during the twenty-four (24) of 24 months reviewed (timeframe: September 2017 to the date of the survey September 12, 2019). Findings include: 1. During a tour of the laboratory on 9/11/19 at approximately 10:00 AM, the inspector noted the following instruments in use for patient immunoassay and routine chemistry testing: Tosoh A1A 900 (serial number 10614302), Horiba Pentra 400 (serial number 305P43270). 2. Review of the manufacturer's operator manuals for ambient operating requirements revealed instructions of required RH%: Tosoh A1A 900: "40-80% humidity is required", Horiba Pentra 400: "Relative humidity must be between 20-85%". 3. Review of the daily temperature/humidity logs for the chemistry testing area during the timeframe of September 2017 to 9/12/19 revealed no record of humidity monitoring. The inspector requested to review the humidity documentation. No records were available for review. 4. In an interview with the laboratory director and primary testing personnel at approximately 12:30 PM on 9/12/19, the above findings were confirmed. B. Based on a tour, review of manufacturer's package inserts, daily temperature logs, quality assurance (QA) policy, and interviews, the laboratory failed to monitor the AGEIS Scientific refrigerator to ensure storage temperature was within acceptable range for C-Peptide (C-P), Free Thyroxine (FT4), Prostate Specific |

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| | Antigen (PSA), and Thyroid Stimulating Hormone (TSH) immunoassay reagents from January 2019 to the date of the survey on September 12, 2019. Findings include: 1. During a tour of the laboratory on 9/11/19 at approximately 10:00 AM, the inspector noted a Tosoh A1A 900 (serial number 10614302) in use for patient immunoassay chemistry testing. The inspector also noted that the Hot Point refrigerator in the laboratory did not contain the all of the test menu Tosoh reagents. The inspector requested to see where the additional Tosoh reagents were stored. The primary TP stated, "We have run out of room in this refrigerator for all of the Tosoh test kits. We started using an extra refrigerator upstairs at the beginning of this year." The primary testing personnel (TP) escorted the inspector to the facility's research nurse's station (on the second floor) at approximately 11:00 AM. The inspector noted an AGEIS Scientific Refrigerator was in use at the research nurse's station to store the following Tosoh reagent kits: four (4) boxes of FT4 (lot number 217531), one (1) box PSA (lot number 128B0), 1 box TSH (lot number 17213), and 2 boxes C-P (lot number 514041). 2. Review of the Tosoh manufacturer's package instructions for the reagent kits outlined above revealed temperature storage requirements to "store 2-8 Celsius". 3. Review of the available temperature logs from January 2019 and up to the date of survey revealed no documentation of monitoring the AGEIS Scientific Refrigerator temperatures. The inspector requested to review the temperature logs. No records were available for review. 4. Review of the laboratory's QA policy revealed the statement: "Temperatures of all appropriate refrigerators and room temperatures are monitored". 5. In an interview with the laboratory director and primary testing personnel at approximately 12:30 PM on 9/12/19, the above findings were confirmed. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of calibration records, procedures, and interviews, the laboratory failed to document calibration procedures for Prostate Specific Antigen (PSA) according to the every ninety (90) day frequency required by the manufacturer from 11/1/18 to 5/27/19. Findings include: 1. Review of the laboratory's 2018 and 2019 Tosoh A1A 900 calibration records revealed PSA calibration documentation on the following dates: 3/20/18, 5/31/18, 7/31/18, 5/28/19 and 7/26/19 2. Review of the A1A 900 Procedure Manual revealed a manufacturer's guideline to calibrate PSA at a frequency of every ninety (90) days. 3. The lab inspector requested calibration records for the seven (7) month lapse in the required 90 day calibration frequency: November 1, 2018 through May 27, 2019. No calibration documentation was available for the timeframe requested. 4. In an interview with the laboratory director and primary testing personnel at approximately 12:30 PM on 9/12/19, the above findings were confirmed. |

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| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), a tour, review of testing personnel (TP) records, quality control (QC), and interviews, the laboratory director (LD) failed to outline, in writing, the non-waived Horiba Pentra 400 patient chemistry testing duties/procedures for two (2) of the three (3) TP in calendar year 2018 and up to the date of the survey on September 12, 2019. Findings include: 1. Review of the CMS 209 personnel form on 9/11/19 at approximately 9:00 AM, revealed 3 testing personnel. (See Personnel Code Sheet.) 2. During a tour of the laboratory on 9/11/19 at approximately 10:00 AM, the inspector noted a Horiba Pentra 400 chemistry analyzer (serial number 305P43270) in use for patient testing. 3. Review of the available personnel records revealed no Horiba Pentra chemistry job designation or performance descriptions for TP A, B, or C. 4. Review of 2018 and 2019 Pentra 400 QC records revealed TP A and B noted as instrument operators. The inspector, at approximately 3:30 PM on 9/11/19, requested to review 2018 Horiba Pentra 400 testing personnel designations /responsibilities for TP A and TP B. No records were available for review. Primary TP (TP A) stated, "I am the primary testing personnel and run the chemistry instruments. I let the other techs run the hematology analyzer." 5. In an interview with the LD and primary TP (TP A) at approximately 12:30 PM on 9/12/19, the above findings were confirmed. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, quality control records, and an interview, the technical consultant (TC) failed to assess annual Horiba Pentra 400 chemistry competency for two (2) of three (3) testing personnel in 2018 and up to the date of the inspection on September 12, 2019. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director also performs the duties of TC and that there were three (3) testing personnel. (See Personnel Code Sheet.) 2. Review of the available personnel records revealed no Horiba Pentra chemistry |

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| | competency assessments in calendar year 2018 and up to 9/12/19 for: TP A, B, C. 3. Review of 2018 and 2019 Pentra 400 QC records revealed TP A and B noted as testing operators. The inspector, at approximately 3:30 PM on 9/11/19, requested to review 2018 Horiba Pentra competency assessments for TP A and TP B. No records were available for review. Primary TP (TP A) stated, "I am the primary testing personnel and run the chemistry instruments. I let the other techs run the hematology analyzer. I had not noticed that the competency assessment page did not include the Pentra instrument". 4. In an interview with the LD and primary TP (TP A) at approximately 12:30 PM on 9/12/19, the above findings were confirmed. |