

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0226649	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier Dominion Medical Associates Inc	Street Address, City, State 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a follow up laboratory tour, review of manufacturer's instructions, and interviews, the laboratory failed to follow Tosoh A1A manufacturer's guidelines for handling of C-Peptide (C-P), Free Thyroxine (FT4), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Vitamin D 25 OH (Vit D) immunoassay test reagents on October 24, 2019. Findings include: 1. During the unannounced follow up tour of the laboratory, at approximately 3:30 PM, the inspector noted the following opened Tosoh A1A chemistry reagent boxes with unopened test cup pouches at room temperature (RT) on a lower shelf in the hematology testing area: C-P lot number 514061, with eighty (80) tests; FT4 lot number J317557, with sixty (60) tests; PSA lot number J1128B7, with one hundred (100) tests; TSH lot number J217228, with 60 tests; Vit D lot number J218750, with 60 tests (the box also included three (3) packs of twenty (20) FT4 tests, lot number J317557). The inspector noted that the Tosoh analyzer's menu displayed current onboard supplies of the reagents listed above. 2. Review of the Tosoh manufacturer box revealed the printed instructions "store 2-8 C". Review of the Tosoh package inserts revealed the following instructions: "All unopened test pouches are stable until the expiration date on label when stored at the specified temperature of 2-8 degrees Celsius." The inspector noted that the reagents listed above did not have open dates or modified expiration dates for storage at room temperature. The inspector inquired how long the test kits had been stored on the shelf at room temperature. The primary testing personnel stated, at approximately 4:30 PM, "We do not have room in our refrigerator</p>

in the lab for the Tosoh reagents. I store them upstairs in the research nurse area in an extra refrigerator. I go up and get what I think we need, and then put the boxes back in the refrigerator at the end of the day with the tests not used". 3. The inspector called the Tosoh technical support number, at approximately 4:55 PM, and inquired of manufacturer's instructions for handling/storage reagent protocols for the A1A. The technical support specialists stated "our package inserts provide strict guidelines for handling test cups once opened and out of the aluminum pouches. The onboard storage is at room temperature and therefore the guidelines for stability are important. We state that unopened boxes or pouches of reagents should be stored at 2-8 C". The technical support specialist provided the following timeframes for stability of opened /onboard analyzer storage of test cups: C-P (7 days), FT4 (24 hours), PSA (24 hours), TSH (24 hours), and Vit D (10 days). The technical support specialist stated "Tosoh does not recommended to repeatedly go from refrigerator to RT and back to refrigerator". 4. In an interview with the primary TP at approximately 5:00 PM, the above findings were confirmed. The primary TP stated, "I have always handled the reagents like this and have had acceptable quality control results".