Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2181786	04/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dentrust Dental Virginia, P C	10101 Brook Road, Glen Allen, 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 initial survey was conducted for Dentrust Dental Virginia on April 12, 2021 by the Virginia Department of Health's Office of Licensure and Certification. An on-site inspection was not performed as the laboratory was no longer open/operating. The survey included a virtual entrance interview conducted on 4/6/21, virtual record review and interviews on 4/8/20, and an exit interview on 4/12/21. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Note that the laboratory was not in compliance with the following Conditions: D5400 - 42 CFR 493.1403 Condition: Analytic Systems; D6076 - 42 CFR. 493.1441 Laboratory Director The specific deficiencies cited are as follows:
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on interviews, review of Centers for Medicare and Medicaid Services 116 form (CMS 116), manufacturer's package inserts, policies/procedures, Centers for Medicare and Medicaid Services 116 form (CMS 116), patient test/quality control (QC) logs, temperature monitoring, and lack of documentation, the laboratory failed to: 1. document monitoring temperatures to ensure proper storage of SD BioSensor Standard Q IgM/IgG Duo immunology kits/reagents while reporting two thousand sixty-eight (2,068) patient antibody results from April 22, 2020 to May 5, 2020; 2. evaluate and verify the performance specifications of a non FDA approved COVID-19 IgG/IgM test method prior to reporting 2,068 patient test results from 4/22/20 to 5/2

	/20; 3. document performance of negative and positive external controls for the non FDA approved COVID-19 IgG/IgM test method for each day of patient testing from 4 /22/20 to 5/5/20 while reporting 2,068 patient results. See D5413, D5423, D5449.
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 review of Centers for Medicare and Medicaid Services 116 form (CMS 116), Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's package insert, policies/procedures, available test logs, interviews, and lack of documentation, the laboratory failed to record monitoring of temperatures to ensure proper storage of immunology kits/reagents while reporting two thousand sixty-eight (2,068) patient COVID-19 IgG/IgM antibody results from April 22, 2020 through May 5, 2020. Findings include: 1. During a pre-survey review process on 04 /06/21, the inspector noted that the laboratory's CMS 116 initial survey form indicated performance of COVID-19 testing by the high complexity test SD BioSensor Standard Q COVID-19 IgM/IgG Duo and that the FDA's published listing of SARS CoV-2 antibody testing EUA's revealed no EUA granted for the utilized kit. 2. Review of the SD BioSensor Standard Q package insert revealed manufacturer's instructions: "Storage and Stability: Store the kit at room temperature, 2-30C / 36-86F, out of direct sunlight". 3. Review of the laboratory's approved procedure, "Dentrust Optimized Care Solutions COVID-19 Laboratory Procedures", revealed no instructions for documentation/monitoring temperatures for proper storage of the high complexity kit/reagents. 4. Review of the available laboratory logs revealed 2,068 patient COVID-19 IgG/IgM antibody test results were reported from 4/22/20 to 5/5 /20. No temperature monitoring logs for the Standard Q test kits conforming with the manufacturer's storage instructions were available for review during the testing timeframe. 5. During the virtual survey on 4/8/21 at approximately 1:00 PM, the inspector requested clarification regarding temperature monitoring of the test kits. The Chief Operating Officer (COO) stated: "We constructed two modular test facilities for the Glen Allen drive through labs and installed generators. No temperatures were recorded for the storage/test areas but the facilities were climate controlled by a generator and it maintained temperature within specified range (36-86 degree F)". 6. A virtual exit interview with the COO on 04/12/21, at approximately 3:00 PM, confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer

must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on review of Centers for Medicare and Medicaid Services 116 form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), interviews, review of available patient and quality control (QC) logs, and lack of documentation, the laboratory failed to evaluate, verify/validate the performance specifications of a high complexity COVID-19 IgG/IgM immunology test method prior to reporting two thousand sixty-eight (2,068) patient COVID-19 IgG/IgM antibody results from April 22, 2020 to May 5, 2020. Findings include: 1. During a pre-survey review process on 04/06/21, the inspector noted that the laboratory's CMS 116 initial survey form indicated performance of COVID-19 testing by the high complexity test SD BioSensor Standard Q COVID-19 IgM/IgG Duo and that the FDA's published listing of EUA's for SARS CoV-2 antibody testing revealed no EUA granted for the utilized test. 2. During a virtual interview of the Chief Operating Officer (COO) on 4/8/21 at approximately 1:00 PM, it was revealed that the laboratory had utilized the high complexity COVID-19 test kits in a drive through testing setting during the timeframe of 4/22/20 through 5/5/20. The inspector asked for a description of the laboratory's QC protocols, to review documentation of in-house validation procedures for the high complexity COVID-19 test method, and patient test logs. The COO stated at approximately 2:00 PM: "We are no longer testing at this site. We did not perform validation studies for the test kits used. We relied on the manufacturer's validation. We used the internal built in QC. We did not purchase extra quality control materials." 3. Review of patient test records and available QC records revealed that the laboratory reported 2,068 patient COVID-19 IgG/IgM antibody test results from 4/22/20 to 5/5/20 while performing zero (0) negative or positive external controls. No records of an approved validation study was available for review. 4. Review of the FDA's posted COVID-19 Removed From Testing Notices, revealed that the SD BioSensor Standard Q COVID-19 IgM/IgG Duo had been identified to be removed from testing as of June 19, 2020. Review of the FDA's removal statement revealed the following provider instructions: "The removed test list includes tests where significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner, tests for which an Emergency Use Authorization request has not been submitted by a commercial manufacturer of a serology test within a reasonable period of time as outlined in FDA's guidance." "The FDA recommends laboratories and health care providers to: A. Stop using the antibody tests listed on FDA's "removed" test list, B. Evaluate, given the patient's clinical presentation and medical history, whether prior test results generated using these tests may have been incorrect, and whether the patient should be retested using an FDA-authorized test, C. Remove from your stock any remaining tests that are listed on FDA's "removed" test list, D. Report any issues with using COVID-19 tests to the FDA." The inspector inquired of records that the lab director had verified/validated the above FDA recommendations. No records were available for review during the virtual survey on 4/8/21. The COO stated at approximately 2:30 PM, "I do not have any validation or verification records for before or after testing at this location". 5. An exit interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), package insert, patient and quality control (QC) logs, and lack of documentation, the laboratory failed to document performance of negative and positive external QC materials for a non FDA approved COVID-19 IgG/IgM test method while reporting two thousand sixty-eight (2,068) patient COVID-19 IgG/IgM antibody results from April 22, 2020 to May 5, 2020. Findings include: 1. In a virtual interview with the Chief Operating Officer (COO) on 4/8/21 at approximately 1:00 PM, it was revealed that the laboratory had utilized the high complexity SD BioSensor Standard COVID-19 test kits in a drive through testing setting during the timeframe of 4/22/20 through 5/5/20. The inspector asked for a description of the laboratory's QC protocols and patient test logs for the test methods outlined above. The COO stated at approximately 2:30 PM: "We used the internal built in QC. We did not purchase extra quality control materials." 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing revealed no EUA granted for test method outlined above. 3. Review of the SD BioSensor Standard Q package insert revealed manufacturer's instructions under Warnings and Precautions: "Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials." 4. Review of the requested laboratory logs revealed that the facility reported 2,068 COVID-19 IgG/IgM results while performing zero (0) negative or positive external controls on fourteen (14) of 14 days of patient testing during the timeframe of 4/22/20 to 5/5/20. 5. An exit interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare and Medicaid Services 116 form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), interviews, and lack of documentation, the laboratory failed to

	retain/provide laboratory reports that included the name and address of the drive through testing facility where high complexity SARS CoV-2 (COVID -19) immunology tests were resulted from April 22 to May 5, 2020. Findings include: 1. Review of the laboratory's CMS 116 initial survey form indicated performance of COVID-19 testing by the high complexity test SD BioSensor Standard Q COVID-19 IgM/IgG Duo and revealed the laboratory name and physical facility location as follows: Dentrust Dental Virginia, PC 10101 Brook Road in Glen Allen, Virginia 23059 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing revealed no EUA granted for test method outlined above. 3. During a virtual interview of the Chief Operating Officer (COO) on 4/8/21 at approximately 1:00 PM, it was confirmed that the laboratory had utilized the Standard Q COVID-19 IgM/IgG high complexity test kits in a drive through testing setting during the timeframe of 4/22/20 through 5/5/20. The inspector inquired if the patient test reports included a statement that acknowledged performance characteristics of the test were determined by the lab director and that the test had not been cleared/approved or given EUA by the U.S. Food and Drug Administration. The inspector requested to review two randomly selected patient COVID -19 reports (from 4/23/20 and 5/4/20). No test reports were available for review. The COO stated at approximately 1:30 PM "We did not provide printed reports. We sent text messages to the patients with negative results and gave verbal reports for positives." 4. An exit interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on interviews, review of Centers for Medicare and Medicaid Services 116 form (CMS 116), the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), FDA's COVID-19 Removed From Testing Notices, available patient testing/quality control (QC)/temperature monitoring logs, policies and procedures, and lack of documentation, the laboratory director failed to: 1. ensure validation/verification performance procedures were performed for a non FDA approved COVID-19 IgG/IgM test method prior to reporting two thousand sixty-eight (2,068) patient COVID-19 IgG/IgM antibody results from 04/22/20 to 05/05/20; 2. ensure that QC policies were established and followed on fourteen (14) of 14 days for a non FDA approved COVID-19 IgG/IgM test method from 04/22/20 to 05/05/20; 3. document performance quality assurance for patient COVID-19 IgG/IgM antibody tests resulted from 04/22/20 to 05/05/20 after the test method had been identified by the FDA as to be Removed From Testing on June 19, 2020. See D6086, D6093, D6099
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services 116 form (CMS 116), Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), patient test and quality control (QC) logs, and lack of documentation, the laboratory director (LD) failed to ensure validation/verification performance procedures were performed for a non FDA approved COVID-19 IgG/IgM test method prior to reporting two thousand sixty-eight (2,068) patient COVID-19 IgG/IgM antibody results from April 22, 2020 to May 5, 2020. (Cross reference D5423) Findings include: 1. During a pre-survey review process on 04/06/21 the inspector noted that the laboratory's CMS 116 initial survey form indicated performance of COVID-19 testing by the high complexity test SD BioSensor Standard Q COVID-19 IgM/IgG Duo and that the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing revealed no EUA granted for the kit outlined. 2. During a virtual interview of the Chief Operating Officer (COO) on 4/8/21 at approximately 1:00 PM, it was revealed that the laboratory had utilized the high complexity COVID-19 test kit kits outlined above in a drive through testing setting during the timeframe of 4/22/20 through 5/5/20. The inspector asked for a description of the laboratory's QC protocols and to review documentation of in-house validation procedures for the high complexity COVID-19 test method. The COO stated at approximately 2:00 PM: "We are no longer testing at this site. We did not perform validation studies for the test kits used. We relied on the manufacturer's validation. We used the internal built in QC. We did not purchase extra quality control materials." 3. Review of available patient test and QC records revealed that the laboratory reported 2,068 patient COVID-19 IgG /IgM antibody test results from 4/22/20 to 5/5/20 while performing zero (0) negative or positive external controls. No records of a LD approved validation study was available for review. 4. An exit interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), package insert, available patient/quality control (QC) logs, policies and procedures, and lack of documentation, the laboratory director failed to ensure that QC policies were established and followed for COVID-19 immunology test from April 22, 2020 to May 5, 2020. (Cross reference D5449) Findings include: 1. In a virtual interview with the Chief Operating Officer (COO) on 4/8/21 at approximately 1:00 PM, it was revealed that the laboratory had utilized the high complexity SD BioSensor Standard COVID-19 test kits in a drive through testing setting during the timeframe of 4/22/20 through 5/5/20. The inspector asked for a description of the laboratory's QC protocols for the test method outlined above. The COO stated at approximately 2:30 PM: "We used the internal built in QC. We did not purchase extra quality control materials." 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing revealed no EUA granted for test method outlined above. 3. Review of the SD BioSensor Standard Q

	package insert revealed manufacturer's instructions under Warnings and Precautions: "Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials." 4. Review of available patient logs revealed that the facility reported 2,068 COVID-19 IgG/IgM results while performing zero (0) negative or positive external controls for fourteen (14) of 14 days of patient testing during the timeframe of 4/22/20 to 5/5/20. 5. Review of the laboratory's provided policy and procedures revealed no written approved QC policy for the high complexity COVID-19 IgG/IgM test kits outlined above. 6. An interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.
D6099	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(9) The laboratory director must ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted Centers for Medicare and Medicaid Services 116 form (CMS 116), Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), interviews, review of the FDA's COVID-19 Removed From Testing Notices, patient test logs, quality control (QC), and lack of documentation, the laboratory director (LD) failed to document quality assurance of COVID-19 test performance for two thousand sixty-eight (2,068) patient COVID-19 IgG/IgM antibody tests resulted from April 22, 2020 to May 5, 2020 after the test method had been identified by the FDA as removed from testing on June 19, 2020. 1. During a pre-survey review process on 04/06/21, the inspector noted that the laboratory's CMS 116 initial survey form indicated performance of COVID-19 testing by the high complexity test SD BioSensor Standard Q COVID-19 IgM/IgG Duo and that the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing revealed no EUA granted for the utilized test. 2. During a virtual interview of the Chief Operating Officer (COO) on 4/8/21 at approximately 1:00 PM, it was revealed that the laboratory had utilized the high complexity COVID-19 test kits outlined above in a drive through test setting during the timeframe of 4/22/20 through 5/5/20. The inspector asked for a description of the laboratory's QC protocols, to review documentation of in-house validation procedures for the high complexity COVID-19 test method, and patient test logs. The COO stated at approximately 2:00 PM: "We are no longer testing at this site. We did not perform validation studies for the test kits used. We relied on the manufacturer's validation. We used the internal built in QC. We did not purchase extra quality control materials." 3. Review of available patient test and QC records revealed that the laboratory reported 2,068 patient COVID-19 IgG/IgM antibody test results from 4/22/20 to 5/5/20 while performing zero (0) negative or positive external controls on fourteen (14) of 14 days. No records of a LD approved validation study was available for review. 4. Review of the FDA's posted COVID-19 Removed From Testing Notices, revealed that SD BioSensor Standard Q COVID-19 IgM/IgG Duo had been identified to be removed from testing as of June 19, 2020. Review of the FDA's removal statement revealed the following provider instructions: "The removed test list includes tests where significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner, tests for which an Emergency Use Authorization request has not been submitted by a commercial

	manufacturer of a serology test within a reasonable period of time as outlined in FDA's guidance." "The FDA recommends laboratories and health care providers to: A. Stop using the antibody tests listed on FDA's removed test list, B. Evaluate, given the patient's clinical presentation and medical history, whether prior test results generated using these tests may have been incorrect, and whether the patient should be retested using an FDA-authorized test, C. Remove from your stock any remaining tests that are listed on FDA's "removed" test list, D. Report any issues with using COVID-19 tests to the FDA." The inspector inquired of quality assurance records that the LD had documented the above FDA recommendations. No records were available for review during the virtual survey on 4/8/21. The COO stated at approximately 2:30 PM, "I do not have any validation or verification records before or after the removal notice". 5. An interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services 116 form (CMS 116), CMS Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical supervisor (TS) failed to document competency assessments that included direct observation of high complexity COVID-19 patient test performance for eight (8) of 8 testing personnel (TP) in 2020. Findings include: 1. During a pre-survey review process on 04/06/21 the inspector noted that the laboratory's CMS 116 initial survey form indicated performance of COVID-19 testing by the high complexity test SD BioSensor Standard Q COVID-19 IgM/IgG Duo. 2. Review of the CMS 209 form revealed the lab director (LD) performed the duties of TS and that 8 TP were indicated as responsible for the high complexity patient testing. The inspector also noted that the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing revealed no EUA granted for the utilized kit. 3. Review of personnel files revealed the laboratory's COVID 19 training records lacked a TS signature or notation of the required competency procedural element of direct observation of routine patient test performance (patient preparation, specimen handling, and testing) for TP #1 - #8. (See Personnel Code Sheet) The inspector requested to review additional competency documentation. The Chief Operations Officer (COO) stated on 4/8/21 at approximately 2:00 PM: "The policy and procedure for the COVID-19 included a signature page for the testing personnel that was electronically signed by each personnel. The lab director did not sign the training." 4. An interview with the COO on 4/12/21 at approximately 3:00 PM, confirmed the above findings.