Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2187903	01/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Total Md Physician Group Pllc	202 Industrial Blvd, Ste 501, Sugar Land, TX	

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	The laboratory was surveyed in response to complaint TX00370229 for compliance with CMS 42 CFR regulations. The laboratory failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY findings: D5300 493.1240: Pre-Analytic Systems D6076 493.1441 Laboratory Director; high complexity The laboratory abated the immediate jeopardy and voluntarily started testing per the EUA approved manufacturer's instructions as evidenced by their letter dated 1/8/21. Complaint TX00370229 was substantiated with 2 of the 4 allegations with deficiencies cited. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of the laboratory's preanalytical studies, review of the laboratory policy, and review of patient records, the laboratory failed to meet the requirements for preanalytic systems, as evidenced by: 1. The laboratory failed to document preanalytical studies for the nasopharyngeal specimens for the qualitative detection of nucleic acid of SARS-CoV-2 using the non EUA approved thermocyler (Mic-PCR) with the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. Refer to D5311-I 2. The laboratory failed to analyze saliva specimens within the manufacturers specimen stability for the qualitative detection of

	SARS-CoV using the FluidIGM Advanta Dx SARS-CoV-2 RT-PCR Assay. Refer to D5311-II 3. The laboratory failed to document a client service manual to include conditions of specimen transport and the specimen acceptability and rejection criteria for the nasopharyngeal specimens for testing with the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit. Refer to D5317
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory failed to document preanalytical studies for the nasopharyngeal specimens for the qualitative detection of nucleic acid of SARS-CoV-2 using the non EUA approved thermocyler (Mic-PCR) with the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. Findings were: 1. Review of the laboratory records revealed the laboratory used the thermocycler Mic-PCR with the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit for the qualitative detection of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in upper respiratory tract fluids (e.g. nasopharyngeal and oropharyngeal swabs) from individuals suspected of COVID-19. 2. Review of the Instructions of Use for the EUA approved test Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (PID-1048-02) under Material Required revealed 1 validated thermocycler CoDx Box (BMS, Bio Molecular Systems). There was no documentation that the Mic-PCR was a validated thermocyler under the EUA approved list. 3. Further review of the Instructions for Use for the EUA approved test Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (PID-1048-02) under Sample Collection, Transport, and Storage revealed "the sample selection, collection, storage, and handling play an essential part in the performance of nucleic acid assays. Thus, valuable information is presented here to help laboratories develop better procedures for the analysis of results and troubleshooting other problems...Nasopharyngeal swab AND oropharyngeal swab (NP /OP swab): use only synthetic fiber swabs with plastic shafts. Do not us
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: %TX_RTF32 14.0.520.503; Based on review of the laboratory policies and confirmed in interview, the laboratory failed to document a client service manual to include conditions of specimen transport and the specimen acceptability and rejection criteria for the nasopharyngeal specimens for testing with the Co-Diagnostics Logix Smart

	Coronavirus Disease 2019 (Covid-19) kit. Findings were: 1. Review of the laboratory client service manual Specimen Collection and Handling for Laboratory Testing of Sars COVID 19 by PCR revealed no documentation of conditions of specimen transport and the specimen acceptability and rejection criteria for the nasopharyngeal specimens for testing with the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit. 2. An interview with the technical supervisor on 1/5/21 at 1615 hours in the office confirmed the above findings. She stated that the laboratory used the client's instructions for their waived Covid-19 test BD VeritorTM System, but she confirmed that the laboratory had not established the specimen requirements for their clients for their test.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and staff interview, the laboratory's quality assurance program failed to detect problems in preanalytic systems. 1. The laboratory failed to document complete preanalytical studies for both nasopharyngeal and saliva specimens for SARS-CoV 2 testing. (Refer to D5311-I, II) 2. The laboratory failed to establish a complete client service manual to include nasopharyngeal specimens. (Refer to D5317)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory records, manufacturer's instructions, review of the CDC (Centers for Disease Control and Prevention) website, surveyor observations, review of the patient test records from December 2020 and January 2021 and confirmed in interview, the laboratory failed to follow manufacturer's instructions for Covid-19 shipment of nasopharyngeal specimens for testing with the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit. Findings were: 1. Review of the laboratory records revealed the laboratory performed SARS-CoV 2 testing testing using the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit starting in December 2020. 2. Review of the Instructions for Use for the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit (PID-1048-02) under Sample Shipping revealed "Specimens known to be, or suspected of, containing SARS-CoV-2 that require shipment by air should be shipped on dry ice as a Biological Substance Category B, UN3373. International regulations, as described in the WHO Guidance on Regulations for the Transport of Infectious Substances 2015-2016, should be followed (CDC, 2020). If ground transportation is needed, the specimen should be shipped frozen overnight with enough ice to keep it frozen

	throughout transit. After the collection of the sample and transfer to the clinical lab, the sample will receive an entry into the laboratory system." 3. Review of the CDC website under Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) under Specimen Packing and Shipping revealed "Pack and ship suspected and confirmed SARS-CoV-2 patient specimens, cultures, or isolates as UN 3373 Biological Substance, Category B, in accordance with the current edition of
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 review of manufacturer's instructions, surveyor observation, and staff interview, it was revealed that the laboratory failed to have documentation of temperature monitoring in the supply room where laboratory supplies for patient testing were stored. Findings include: 1. A review of the manufacturer's instructions for the Gibco PBS 7.4 phosphate buffered saline (10010-031) revealed the storage requirements of 15 - 30C. 2. Surveyor observation, during a tour of the laboratory on 1 /5/21 at 1210 hours, found 146 bottles of Gibco PBS 7.4 phosphate buffered saline in the supply room with no means of temperature monitoring. The Gibco PBS 7.4 phosphate buffered saline is used for the Advanta Dx SARS-CoV-2 RT PCR test run on the Biomark HD System. 3. A review of the laboratory's testing records revealed the laboratory began testing the Advanta Dx SARS-CoV-2 RT PCR test on September 10, 2020 and estimated an annual test volume of 50,000. 4. An interview with technical supervisor #2 (as indicated on the CMS 209 form) on 1/5/21 at 12:35 p.m. in the supply room, stated that she was not aware that the temperature needed to be monitored in the supply room. This 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 the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory failed to document complete establishment studies for the thermocyler (Mic-PCR) not validated for use for the EUA approved test Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. Findings were: 1. Review of the laboratory records revealed the laboratory used the thermocycler Mic-PCR with the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit for the qualitative detection of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in upper respiratory tract fluids (e.g. nasopharyngeal and oropharyngeal swabs) from individuals suspected of COVID-19. 2. Review of the Instructions of Use for the EUA approved test Logix Smart Coronavirus Disease 2019 (COVID-19) Kit (PID-1048-02) under Material Required But not Included with the Test revealed no documentation of the Mic-PCR as a validated thermocyler. 3. Review of the laboratory verification records revealed no documentation of the establishment studies for 1 of 1 Mic-PCR (S/N M0003857) to include the limit of detection, sensitivity, cross reactivity and preanalytical studies. Cross refer to D5311-I 4. Random review of the laboratory patient records from December 2020 to January 2021 revealed the laboratory performed the following 16 SARS-CoV-2 testing using the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit with the unapproved thermocylcer Mic-PCR. Date: 01/03/2021 STEAMEC0001096 STEAMEC0001112 STEAMEC0001113 STEAMEC0001097 date: 01/02/2021 STEAMEC0001086 STEAMEC0001090 Date: 01/04/2021 STEAMEC0001122 STEAMEC0001123 STEAMEC0001126 Date: 12/29/2020 STEAMEC0001024
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory records, surveyor observations, patient test records, and confirmed in interview, it was revealed the laboratory quality assessment failed to identify and correct problems in the analytic systems. Refer to D5411, D5423
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: TX_RTF32 14.0.520.503; Based on review of laboratory's policy, patient test records, and manufacturer's instructions, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure quality laboratory services for high complexity preanalytic and analytic

	systems. Refer to D6082. 2. The laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services. Refer to D6094.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's preanalytical studies, surveyor observation of specimens received by the facility, patient records, laboratory policy, laboratory establishment studies, and patient records, the laboratory director failed to ensure quality laboratory services for high complexity preanalytic and analytic systems, as evidenced by: 1. The laboratory failed to document preanalytical studies for the nasopharyngeal specimens for the qualitative detection of nucleic acid of SARS-CoV-2 using the non EUA approved thermocyler (Mic-PCR) with the Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. Refer to D5311-I 2. The laboratory failed to analyze saliva specimens within the manufacturers specimen stability for the qualitative detection of SARS-CoV using the FluidIGM Advanta Dx SARS-CoV-2 RT-PCR Assay. Refer to D5311-II 3. The laboratory failed to document a client service manual to include conditions of specimen transport and the specimen acceptability and rejection criteria for the nasopharyngeal specimens for testing with the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit. Refer to D5317 4. The laboratory failed to follow manufacturer's instructions for Covid-19 shipment of nasopharyngeal specimens for testing with the Co-Diagnostics Logix Smart Coronavirus Disease 2019 (Covid-19) kit. Refer to D5411 5. The laboratory failed to document complete establishment studies for the thermocyler (Mic-PCR) not validated for use for the EUA approved test Logix Smart Coronavirus Disease 2019 (COVID-19) Kit. Refer to D5423
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 review of the manufacturer's instructions, laboratory's preanalytical studies, laboratory policies, surveyor observation of specimens received by the facility, patient records, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services, as evidenced by: 1. The laboratory failed to establish and follow written policies/procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Refer to D5391. 2. The laboratory failed to

	establish and follow written policies/procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791.
D6174	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the submitted CMS 209 form, a review of the laboratory's personnel records, a review of the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to ensure that 7 of 7 testing personnel performed tests authorized by the laboratory director. Findings include: 1. A review of the laboratory's policy titled 'Personnel SOP' revealed the following: "Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities." 2. A review of the submitted CMS 209 form revealed the laboratory employed 7 testing personnel to perform the Advanta Dx SARS-CoV-2 RT PCR test run on the Biomark HD System (high complexity). 3. A review of the laboratory's personnel records revealed no documentation of the laboratory director's authorization to test for the 7 testing personnel. 4. A review of the laboratory's testing records revealed the laboratory began testing the Advanta Dx SARS-CoV-2 RT PCR test on September 10, 2020 and estimated an annual test volume of 50,000. 5. An interview with the laboratory director on 1/5/21 at 4:23 p.m. in the office, confirmed the above findings.