Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2241674	09/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
D&G Medical Associates Pllc	1430 W Ustick Rd Ste 100, Meridian, ID	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a lack of laboratory documents and an interview with the laboratory director on 9/26/2022, the laboratory failed to enroll in proficiency testing (PT) for the QIAstat respiratory SARS-CoV-2 panel testing since beginning testing in February of 2022. The findings include: 1. A lack of laboratory records identified that the laboratory failed to perform PT for the QIAstat respiratory SARS-CoV-2 panel testing that included the following analytes; Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, SARS-CoV-2, Human Metapneumovirus A+B, Influenza A, Influenza A H1, Influenza A H3, Influenza A H1N1/pdm09, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus A+B, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae since beginning patient testing on February 15, 2022. 2. An interview with the laboratory director on 9/26/2022 at 1:18 pm confirmed that the laboratory failed to enroll and perform PT for the QIAstat respiratory SARS-CoV-2 panel testing. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panel tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a lack of laboratory documents and an interview with the laboratory director on 9/26/2022, the laboratory failed to verify the accuracy of testing at least twice annually for SARS-CoV-2 testing since beginning testing in February of 2022. The findings include: 1. A lack of laboratory records identified that the laboratory failed verify the accuracy of testing at least twice annually for SARS-CoV-2 included in the QIAstat respiratory SARS-CoV-2 panel testing since beginning patient testing on February 15, 2022. 2. An interview with the laboratory director on 9/26/2022 at 1:18 pm confirmed that the laboratory failed to verify the accuracy of testing at least twice annually for SARS-CoV-2 testing. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 tests annually.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on a review of laboratory records and an interview with the laboratory director on 9/26/2022, the laboratory failed to have a test requisition for QIAstat respiratory SARS-CoV-2 panel testing. The findings include: 1. A review of laboratory records identified that the laboratory failed to have a written test requisition that included the authorized test requester and contact information, the patients name, date of birth, testing to be performed, source of specimen, date and time of collection. 2. An interview with the laboratory director on 9/26/2022 at 1:22 pm confirmed that the laboratory failed to have a test requisition. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panels annually.
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 for use (IFU), a direct observation, lack of laboratory records and an interview with the laboratory director on 9/26/2022, the laboratory failed to establish and document the correct storage temperature of quality control (QC) and patient samples . The findings include: 1. A review of the manufacturer's IFU for the QIAstat respiratory SARS-CoV-2 panel identified that samples can be stored at room temperature (15 to 25 C), refrigerated (2 to 8 C) or frozen (-15 to -25 C). 2. A direct observation of ZepoMetrix QC in the refrigerator identified a storage temperature of 2 to 8 C. 3. A lack of laboratory records identified that the laboratory failed to document refrigerator, freezer and room temperature since beginning patient testing in February 2022. 4. An interview with the laboratory director on 9/26/2022 at 1:26 pm confirmed the above findings. 5. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panel test annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a lack of quality control (QC) records for the QIAstat respiratory SARS-CoV-2 panel and an interview with the laboratory director on 9/26/2022, the laboratory failed to perform QC once each day of patient testing. The findings include: 1. A review of the laboratory's policies and procedures identified that the laboratory failed to have an Individualized Quality Control Plan (IQCP) for the QIAstat respiratory SARS-CoV-2 panel testing. 2. A lack of QC documents for the QIAstat respiratory SARS-CoV-2 panel identified that the laboratory failed to perform QC each day of patient testing since begining testing on February 15, 2022. 3. An interview with the laboratory director on 9/26/2022 at 1:16 pm confirmed that the laboratory did not have an IQCP for the QIAstat respiratory SARS-CoV-2 panel and had not performed QC since the test validation in February 2022. 4. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panels annually.
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 patient laboratory test reports and an interview with the laboratory director on 9/26/2022, the laboratory failed to indicate the name and address of the performing laboratory, patients full name and unique patient identifier and specimen source for QIAstat respiratory SARS-CoV-2 panel testing. The findings include: 1. A review of patient laboratory test reports for QIAstat respiratory SARS-CoV-2 panel identified that the laboratory failed to indicate the name and address of the performing laboratory, the patients full name and second identifier for positive identification and the source of the specimen. 2. An interview with the laboratory director on 9/26/2022 at 1:24 pm confirmed that the name and address of the performing laboratory, patients full name and second identifier and specimen source was not indicated on the test report. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panel tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient test reports and an interview with the laboratory director on 9/26/2022, the laboratory failed to include the normal values for the reported for QIAstat respiratory SARS-CoV-2 panel analytes on patient test reports. The findings include: 1. A review of patient laboratory test reports identified that the laboratory failed to include the normal values for the analytes of the QIAstat respiratory SARS-CoV-2 panel; Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, SARS-CoV-2, Human Metapneumovirus A+B, Influenza A, Influenza A H1, Influenza A H3, Influenza A H1N1/pdm09, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus A+B, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae. 2. An interview with the laboratory director on 9/26/22 at 1:24 pm confirmed that the laboratory failed to list normal values on the patient reports for the QIAstat respiratory SARS-CoV-2 panel. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panel tests annually.
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 a review of laboratory documents, a lack of documents and an interview with the laboratory director (LD) on 9/26/2022, the laboratory director failed to fulfill his responsibilities and oversee the operation of the laboratory. The LD failed to ensure enrollment in proficiency testing (D6015), failed to establish and maintain a quality control program (D6020), and failed to ensure that patient reports had pertinent information for patient identification and test interpretation (D6026) for QIAstat respiratory SARS-CoV-2 panel testing.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a lack of laboratory records and an interview with the laboratory director on 9/26/2022, the laboratory director failed to ensure enrollment in proficiency testing (PT) for the QIAstat respiratory SARS-CoV-2 panel testing since beginning testing in February of 2022. The findings include: 1. A lack of laboratory records identified that the laboratory failed to perform PT for the QIAstat respiratory SARS-CoV-2 panel testing. See D2000 2. An interview with the laboratory director on 9/26/2022 at 1:18 pm confirmed that the laboratory failed to enroll and perform PT for the QIAstat respiratory SARS-CoV-2 panel testing. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panel tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, a lack of quality control (QC) records for the QIAstat respiratory SARS-CoV-2 panel and an interview with the laboratory director on 9/26/2022, the laboratory director failed to establish a QC program. The findings include: 1. A lack of QC records identified that the laboratory director failed to ensure QC was performed for QIAstat respiratory SARS-CoV-2 panel testing each day of patient testing. See D5445 2. An interview with the

	laboratory director on 9/26/2022 at 1:16 pm confirmed that the laboratory had not performed QC since the testing validation in February 2022. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panels annually.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of patient laboratory reports and an interview with the laboratory director on 9/26/2022, the laboratory director failed to ensure that proper information was on the report to identify the patient and interpret results for QIAstat respiratory SARS-CoV-2 panel testing. The findings include: 1. A review of patient laboratory test reports for QIAstat respiratory SARS-CoV-2 panel identified that the laboratory failed to indicate the name and address of the performing laboratory, the patients full name and second identifier for positive identification and the source of the specimen. See D5805 2. A review of patient laboratory test reports identified that the laboratory failed to include the normal values for the analytes of the QIAstat respiratory SARS-CoV-2 panel. See D5807 3. An interview with the laboratory director on 9/26/2022 at 1:24 pm confirmed that they failed to ensure that pertinent information needed for patient identification and test interpretation was on the test report. 3. The laboratory reports performing 20 QIAstat respiratory SARS-CoV-2 panel tests annually.