Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2182592	11/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mriglobal Clinical Laboratories	65 Watkins Mill Rd, Gaithersburg, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the procedure and extraction worksheet and interview with the testing personnel (TP), the laboratory's procedure failed to provide instructions for how to process the extraction controls for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing. Findings: 1. The procedure titled "MRIGlobal Clinical Laboratories Sample Testing using the CDC 2019-Novel coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel" was reviewed. 2. The section titled "6. Materials Required for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel"

	stated that the "Extraction Control" was a "Human specimen control" or "contrived negative human specimen, or a suspension of any human cell line in PBS." 3. The section titled "9. Quality Control" stated that an "external extraction positive control, an external extraction negative control, an external PCR positive control and a No Template Control will be included in each run." It was explained that the external extraction positive control (EPC) consisted of SARS-CoV-2 virus spiked into nasal wash or human matrix medium and the external extraction negative control was the CDC Human Specimen Control (HSC). 4. The laboratory utilized a RNA Extraction Worksheet to document each step of the extraction procedure for each testing batch of patient specimens. The worksheet included instructions for preparing the extraction buffer based on the total number of patient specimens plus the EPC and HSC, which were to be extracted with the patient specimens. 5. Sections 8.5.1 and 8.5.2 of the testing procedure which described the steps to prepare the extraction reagents and perform the RNA extraction did not include instructions for accounting for the extraction controls when calculating the total extraction buffer volume and for extracting the EPC and HSC with the patient specimens as was described in the RNA Extraction Worksheet. 6. During the survey on 11/10/2021 at 1:30 PM, the TP confirmed that the SARS-CoV-2 RT-PCR testing procedure did not specify how to process the positive and negative extraction controls through the extraction procedure.
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: I. Based on instrument manual and temperature log record review and interview with the technical supervisor (TS), the laboratory failed to define, monitor, and document laboratory room temperature and room humidity to ensure reliable test system operation. Findings: 1. The laboratory performs severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing on an Applied Biosystems 7500 Fast Real-Time PCR System (AB 7500). 2. The instrument's "Applied Biosystems 7500/7500 Fast Real-Time PCR System Site Preparation Guide", under subheading, "Environmental Requirements Checklist" states "Recommended operating conditions: Temperature: 15 to 30 C (59 to 86 F). Maximum change of less than 15 degrees Celsius (27 F) per 24 hrs. Humidity: 20 to 80% relative humidity, noncondensing." 3. Record review showed that there were no logs documenting the temperature or humidity present in the laboratory where the AB 7500 was operated. 4. During an interview on 11/10/2021 at 1:00 PM the TS confirmed that the laboratory did not monitor room temperature and humidity in the laboratory where the AB 7500 was operated and that the laboratory failed to ensure reliable test system operation by defining acceptable room temperature and humidity ranges and documenting room temperatures and humidity in the laboratory. II. Based on temperature log record review and interview with the technical supervisor (TS), the laboratory failed to define, monitor, and document laboratory reagent freezer temperature to ensure proper reagent storage and reliable

	test system operation. Findings: 1. The laboratory has been in operation from January, 2021 to present. "Temperature Monitoring Logs" were reviewed from January through November, 2021 for the "Magic Chef" laboratory freezer (MRIGlobal ID Y-21443). This is where the laboratory stores the "master mix" reagent used for its polymerase chain reaction testing. 2. Record review showed that freezer temperatures were documented for 3 days in January, 4 days in February, 9 days in March, 5 days in April, 4 days in May, 5 days in June, 4 days in July, 1 day in August, 2021, and 1 day in September, 2021. No freezer temperatures were documented in October or November, 2021. 3. During an interview on 11/10/2021 at 1:20 PM, the TS confirmed that the laboratory failed to define acceptable temperature ranges and document laboratory freezer temperatures to ensure proper reagent storage and reliable test system operation.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on instrument maintenance record and instrument manual review and interview with the testing personnel (TP) and technical supervisor (TS), the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings: 1. The laboratory performs severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) reverse transcription polymerase chain reaction (RT-PCR) testing on an Applied Biosystems 7500 Fast Real-Time PCR System (AB 7500). 2. During an interview at 1 PM on the day of the survey the TP stated that the background calibration should be run monthly. The instrument's "Applied Biosystems 7500/7500 Fast Real-Time PCR Systems System Maintenance" manual states "Perform a background calibration" "monthly, or as often as necessary, depending on instrument use." 3. A review of "Equipment Service Records" for the AB 7500 from January through October, 2021 showed that the background calibration was performed on 02/19/2021, 04/14/2021, 06/2/2021, 08/2 /2021, and 10/6/2021. Background calibrations were not performed 5 out of 10 months in 2021. 4. During an interview on 11/10/2021 at 1:20 PM the TS confirmed that the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.