Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1041510	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gamma Healthcare, Inc - Poplar Bluff	1717 West Maud St, Poplar Bluff, MO	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation and interview, the laboratory failed to maintain a uni-directional workflow process to prevent contamination for COVID-19 PCR testing (Refer to D3005).
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation of the COVID-19 testing room and interview with the general supervisor (GS) #1, technical supervisor (TS) #2, and testing personnel (TP) #7, the laboratory fails to have a uni-directional workflow that includes separate areas for

	specimen preparation, amplification, and product detection for COVID-19 using the Taq-Path PCR testing. Uni-directional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination of patient specimens, and consists of separate areas for reagent preparation, pre-amplification, and post-amplification. Findings: 1. Observation of the COVID-19 testing room showed two hoods located next to each other for processing and setting up the patient extraction 96 well plate, one desk area for reaction tray and quality control (QC) setup next to one of the hoods, two King Fischer extractors located diagonally from the processing hoods, four Applied Biosystems 7500 Fast Real Time PCR analyzers located in the middle of the room, one refrigerator, which stores COVID-19 specimens, one freezer next to one centrifuge, and one freezer with the positive control next to the KingFischer extractors. 2. Interview on October 6, 2020 at 11:45 AM with GS #1 and TP #7 confirmed "on day shift, the tech walks across the room to get the samples out of the refrigerator and takes to the hood. The tech makes up the first 96 well plate patient extraction tray, walks across the room to put it on the KingFischer extractor, cleans the area with alcohol and begins to setup the second 96 well patient extraction tray. On evening shift, two techs are setting up a total of two each, 96 well patient extraction trays. They start the second tray after the first patient tray is on the extractor. After the extraction is completed on the KingFischer, the tech carries the tray back to the hood for reaction tray processing and then puts the tray on the 7500 Fast Track PCR analyzers." These analyzers are located in the middle of the room. The TP walk across the room and back to the setup areas several times to obtain reagents, specimens, quality control, and supplies. 3. Interview on October 6, 2020 at 12:00 PM with the TS #2 and GS #1 confirmed the laboratory failed to have a uni-directional workflow to include separate areas to prevent contamination of patient specimens, equipment, instruments, reagents, materials, and supplies.
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 manual and interview with the technical supervisor (TS) #1, the laboratory failed to have a step-by-step procedure for verification

	procedures used to determine the accuracy, precision, reportable range, normal range, sensitivity, and specificity of four of four Applied Biosystems 7500 Fast Real Time PCR analyzers for COVID-19 testing. FIndings: 1. No procedure was available for review for verification procedures used to determine the accuracy, precision, reportable range, normal range, sensitivity, and specificity of four of four Applied Biosystems 7500 Fast Real Time PCR analyzers for COVID-19 testing. 2. Interview with the TS #1 on October 6, 2020 at 2:00PM confirmed the laboratory failed to have a step-by-step procedure for verification procedures determine the accuracy, precision, reportable range, normal range, sensitivity, and specificity of four of four Applied Biosystems 7500 Fast Real Time PCR analyzers for COVID-19 testing.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of maintenance documentation, procedure manual and interview with the general supervisor (GS) #1, the laboratory failed to perform a function check protocol to verify the accuracy of two Thermo Scientific MLA pipettes for COVID-19 testing. Findings: 1. Review of pipette calibration documentation showed the last calibration for the 1-10 microliter multichannel pipette was August 29, 2019 and the last pipette calibration for the Thermo Scientific MLA 2-20 microliter was June 6, 2019. 2. Review of the procedure manual revealed "Pipettes are calibrated annually. Results are reviewed by the lab supervisor. Pipettes that fail the validation are taken out of service." 3. Interview with the GS#1 on October 6, 2019 at 12:00 PM confirmed, the laboratory failed to perform a function check to verify the accuracy of the volumes of two Thermo Scientific MLA pipettes for COVID-19 testing.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of documentation, observation of two of two new Applied Biosystems 7500 Fast Real Time PCR analyzers, and interview with the general supervisor (GS)

	#1 and the Information Technology Manager, the laboratory failed to ensure test results and patient specific data was reliably sent from the Applied Biosystems 7500 Fast Real Time PCR analyzers to the laboratory information system (LIS). Findings: 1. Observation of the COVID-19 testing room showed two new Applied Biosystems 7500 Fast Real Time PCR analyzers put into use August 14, 2020. 2. Review of documentation revealed the laboratory failed to check patient data and test results sent from two of two new Applied Biosystems 7500 Fast Real Time PCR analyzers to the LIS. 3. Review of documentation emailed from the Information Technology Manager on October 7, 2020 at 8:35 AM confirmed the laboratory failed to check patient test results and patient specific data electronically transmitted from the two new Applied Biosystems 7500 Fast Real Time PCR analyzers to the LIS for accuracy.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a lack of available delegation of duties for the general supervisor (GS) and interview with GS #1, the laboratory director (LD) failed to specify in writing the responsibilities of the GS. Findings: 1. No written delegation of duties was available for GS #1. 2. GS #1 performed training of four of seven testing personnel. 3. Interview with GS #1 on October 6, 2020 at 1:00 PM confirmed the LD failed to specify in writing the responsibilities of the GS.