Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1041510	07/01/2020
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
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 review of Applied Biosystems 7500 Fast Real Time PCR (TaqPath) procedure, patient test reports, review of quality assurance (QA) policy, and interviews, the laboratory director (LD) failed to provide overall management and direction to the laboratory. The LD failed to ensure verification procedures for the TaqPath included performance specifications for interfering substances (Refer to D6086); failed to ensure testing personnel are performing TaqPath COVID-19 test methods as required for accurate and reliable results (Refer to D6087); and failed to ensure staff identify problems and potential problems in real time for COVID-19 PCR patient testing (Refer to D6094).
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 Applied Biosystems 7500 Fast Real Time PCR (TaqPath) of the laboratory's verification of performance specifications, patient test volumes and interview with the technical supervisor #2, the laboratory failed to establish

	performance specifications to include interfering substances, for the TaqPath COVID-19 test before reporting patient test results. Findings: 1. Review of the laboratory's validation reports for performance specifications of the TaqPath instrumentation revealed the laboratory failed to verify specificity for interfering substances for COVID-19 testing prior to performing patient testing on April 7, 2020. 2. Approximately 26,239 patients have been tested for COVID-19 since April 7, 2020. 3. Interview with the technical supervisor #2 on July 1, 2020 at 10:00 AM confirmed the laboratory failed to establish performance specifications for interfering substances before reporting patient test results.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of Taq Path COVID-19 PCR procedure, five of five patient test reports for COVID-19, email correspondences with Thermo Fischer technical support, interviews with testing personnel (TP) #15, technical supervisor (TS) #2, Thermo Fischer technical support, and the laboratory owner, the laboratory director (LD) failed to ensure TP perform the test methods as required for accurate and reliable results. Findings: 1. Review of the COVID-19 Taq Path PCR procedure showed "Prepare the processing plates according to the following table.... Cover the plates with a temporary seal (such as MicroAmp (Trademark) Clear Adhesive Film), then store at room temperature for up to 1 hour while you set up the sample plate....Use separate areas for the preparation of patient samples and controls....Place the Elution Plate on ice for immediate use in real-time RT-PCR. False-positive results may arise from: - Cross contamination during specimen handling or preparation - Cross contamination between patient samples - Specimen mix-up - RNA contamination during product handling " 2. Interview on July 1, 2020 at 10:30 AM, TP #15 stated, "I make up the plates for the King Fischer extractor in the morning, cover with the film and keep them at room temperature until the specimens are ready to go on the extractor. I also make up the 96 well plate with the specimens, seal it, and store the plate in the refrigerator with the specimens for COVID until the King Fischer extractor is ready for processing....all specimens and controls are made up under the hood. I do not put the elution plate on ice." 3. Phone interview with Thermo Fischer Technical Application Scientist on July 2, 2020 at 8:30 AM, confirmed "Once the specimen testing process for COVID is started, there should be no stoppage until extraction. The premade King Fischer extraction plates are only good for up to one hour at room temperature. Controls and specimens need to be processed in a separate area to prevent contamination...the elution plate needs to be placed immediately on ice." 4. Review of five patient test reports for COVID-19 showed the laboratory reported out inconsistent results for: Patient A 6/10/20 patient test result "not detected" 6/24/20 patient test result "positive" 6/29/20 patient test result "not detected" Patient B 6/24/20 patient test result "positive" 6/29/20 patient test result "not detected" Patient C 6/27/20 patient test result "positive" 6/29/20 patient test result from laboratory B "negative" Patient D 6/27/20 patient test result "positive" 6/29/20 patient test result from a laboratory B "negative" Patient E 6/27/20 patient test result "positive" 6/29/20 patient test result from laboratory B "negative" 5. Review of email correspondences with Thermo Fischer senior field application scientist sent June 29, 2020 at 9:13 PM revealed, "That is a suspiciously high number of positive samples in

	one plate.....My initial assessment is that there is significant contamination. I can't say for sure if this might have happened at the extraction or PCR steps but I would repeat the samples from this batch." Another email sent on June 30, 2020 at 8:31 AM revealed, ".....It is important to always use clean, new plasticware whenever working with these reagents and never return reagents to their stock containers. A new bottle of water should be opened and aliquoted into single use tubes of an appropriate volume based on the workflow and once opened and used, they should then be discarded. It is also acceptable to aliquot any, or all, of the extraction or PCR reagents into new tubes or bottles. Working from stock bottles, especially bottles which contain enough reagent to process up to 2000 samples, is always a potential source of contamination....." 6. Review of email correspondence with Thermo Fischer technical application scientist sent on June 30, 2020 at 11:01 AM revealed, "I have looked at the data file you sent. I also think that there is contamination by MS2 control...." 7. Interview with TS #2 and the laboratory owner on July 1, 2020 at 10:30 AM, confirmed the LD failed to ensure TP are performing the test methods as required for accurate and reliable results. 38475
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 laboratory's quality assessment (QA) program, patient COVID-19 testing records for June 2020, and interview with technical supervisor #2, the laboratory director failed to maintain the QA program and identify failures as they occur. The laboratory failed to establish criteria for accepting or rejecting 152 of 152 patient test batches during June 2020 based on positivity rate for COVID-19 patient testing. Findings: 1. The QA program states, "It is the duty of each employee to identify problems and potential problems, to correct these on the spot or report these to their supervisor if it is beyond their capacity to correct the problem. The manager of laboratory operations, director of technical services and the laboratory director have the overall responsibility for managing problems related to the quality of their laboratory work." 2. The QA program did not establish criteria for identifying problems or potential problems for positivity rates associated with COVID-19 PCR patient batchs (runs) to determine acceptability or rejection. 3. Review of COVID-19 PCR testing records from June 2, 2020 through June 27, 2020 showed the following positivity (pos) rates: June 3, 2020 Batch ID Pos. Rate Patients tested HW 25.30% 83 patients tested LRT 25.84% 89 patients tested June 4 , 2020 Batch ID Pos. Rate Patients tested HW1A 21.79% 78 patients tested RP-LRT 22.54% 71 patients tested June 5, 2020 Batch ID Pos. Rate Patients tested LRT1A 21.21% 99 patients tested June 6, 2020 Batch ID Pos. Rate Patients tested RMP 25.33% 75 patients tested June 10, 2020 Batch ID Pos. Rate Patients tested HW 29.35% 92 patients tested June 19, 2020 Batch ID Pos. Rate Patients tested RMP1 62.82% 78 patients tested June 23, 2020 Batch ID Pos. Rate Patients tested RMP4 19.77% 86 patients tested June 26, 2020 Batch ID Pos. Rate Patients tested RMP1 23.33% 90 patients tested HW3A 21.33% 75 patients tested June 27, 2020 Batch ID Pos. Rate Patients tested RMP2 54.35% 92 patients tested 4. The laboratory did not detect or identify problems or potential problems regarding positivity rates as it occurred or before patient results were reported to clients. 5. Interview with technical supervisor #2 on July 1, 2020 at

	10:30 AM confirmed the laboratory director failed to ensure staff identify problems and potential problems in real time for COVID-19 PCR patient testing. Technical supervisor # 2 said the laboratory contacted manufacturer technical support on June 29, 2020 and confirmed the positivity rates were problematic and required investigation and corrective action.