

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D1041510	(X3) Date Survey Completed 06/23/2020
Name of Provider or Supplier Gamma Healthcare, Inc - Poplar Bluff	Street Address, City, State 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
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the microbiology area and interview with the technical supervisor (TS) #2, the laboratory failed to be arranged to ensure adequate space for conducting all phases of the testing process. Findings: 1. Observation of the microbiology laboratory showed three Vitek 2 analyzers for microbiology testing located next to two Applied Biosystems 7500 Fast Real Time PCR analyzers and the King Fischer RNA Extractor for COVID-19 testing. The King Fischer RNA Extractor was situated next to the microbiology specimen media plating bench. 2. Observation of the room temperature in the microbiology laboratory showed a temperature of 76 degrees Fahrenheit. Observation of the microbiology laboratory showed one Vitek MS analyzer located in the middle of the room within two feet of the specimen processing area. The microbiology area was crowded with the potential of specimen contamination. 3. Observation of the microbiology laboratory showed only one hood for processing specimens for COVID-19 testing. The laboratory failed to have another ventilation hood to process microbiology specimens. 4. Interview with the TS #2 on June 22, 2020 at 11:30 AM confirmed the laboratory failed to be arranged to prevent contamination of patient specimens.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous</p>

materials.

This STANDARD is not met as evidenced by:

Based on the lack of COVID-19 safety procedures, observation of one of four testing personnel (TP) for high complexity COVID-19 testing, and interview with the technical supervisor (TS) #2, the laboratory failed to ensure a safe environment from biological hazards associated with COVID-19. Findings: 1. The laboratory could not provide written procedures to show it established safety procedures for collecting, processing, and testing COVID-19 specimens. 2. Observation of COVID-19 testing showed TP #15 was pipetting COVID-19 specimens in the microbiology laboratory with a N95 mask that was not fitted properly and hanging off the face of TP #15. 3. Interview with TS #2 on June 22, 2020 at 11:30 AM confirmed the LD failed to establish policies and procedures for activities associated with COVID-19 testing.

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:

Based on review of laboratory policies and procedures, patient testing volume and email correspondence with technical supervisor (TS) #2, the laboratory failed to establish written policies for specimen submission, handling and referral for COVID-19 (SARS-CoV-2 RT PCR) specimens Findings: 1. The laboratory did not establish written policies and procedures for each of the following: a) Patient preparation b) Specimen collection c) Specimen storage and preservation d) Conditions for specimen transportation e) Specimen acceptability and rejection f) Specimen referral 2. Patient testing volumes retrieved by TS #2 showed the laboratory processed 26,239 PCR specimens beginning April 7, 2020 through June 22, 2020. 3. Email correspondence on June 22, 2020 at 4:03 PM with TS #2 confirmed the laboratory did not have a formal policy to address specimen acceptability, submission, handling and rejection for COVID-19 testing.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures and email correspondence with technical supervisor (TS) #2, the laboratory failed to ensure COVID-19 procedures were approved, signed and dated by the current laboratory director before use. Findings: 1. The laboratory could not provide documentation to show the laboratory director approved, signed, and dated COVID-19 procedures performed on the Architect

	<p>(SARS CoV IgG antibody) and Applied Biosystems 7500 Fast Real Time PCR instrumentation (SARS CoV-2-RT-PCR). 2. Email correspondence with TS #2 on June 22, 2020 at 4:30 PM confirmed the laboratory could not provide approved, dated and signed COVID-19 testing procedures by the current laboratory director.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: 35554 Based on review of observations, verification procedures and interviews, the laboratory director failed to ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards (refer to D6084); failed to ensure verification (validation) procedures were adequate for the instrument prior to patient testing (refer to D6086), and failed to ensure all personnel received appropriate training prior to testing COVID-19 specimens on the PCR instrumentation (refer to D6102).</p>
<p>D6084</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.</p> <p>This STANDARD is not met as evidenced by: 35554 Based on observation of the microbiology laboratory and interview with the technical supervisor (TS) #2, the laboratory director failed to provide a safe environment in which employees are protected from physical, chemical and biological hazards. Findings: 1. Observation of the microbiology plating area showed a countertop with media plates and urine specimens. No ventilation hood for plating microbiology specimens was available for testing personnel to prevent exposure to biohazardous specimens. 2. Interview with TS #2 on June 22, 2020 at 11:30 AM confirmed the laboratory director failed to provide proper ventilation and a shield barrier to ensure personnel is protected from biological hazards.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of cohesive verification procedures for COVID-19 testing for two of two Applied Biosystems 7500 Fast Real Time PCR instruments, review of</p>

verification procedures for COVID-19 IgG antibody testing on the Architect instrument, patient testing volume and email correspondence with technical supervisor (TS) #2 confirmed, the laboratory director failed to ensure verification procedures were adequate before patient testing started. Findings: 1. The laboratory could not provide cohesive and approved verification procedures for the Applied Biosystems 7500 Fast Real Time PCR instruments prior to patient testing for COVID-19. In an email addressed to the laboratory director dated April 7, 2020 at 3:56 PM TS #2 stated "I've attached the raw data of our study for your review. I'll package it more neatly later if that is okay with you." We are ready to start testing as soon as you approve unless there is something else you think we need to do." In an email addressed to the laboratory director dated June 22, 2020 at 1:52 PM TS #2 stated, " I don't have your signature that you approved our validation data for the 7500 DX. Could you respond to this email indicating approval." The laboratory director responded 8 minutes later at 2:00 PM by email. The laboratory director stated, 'this confirms review and discussion regarding use of the 7500 DX following validation." 2. Review of COVID-19 antibody verification procedures performed on the Architect instrument revealed no documentation to show approval by the laboratory director. 3. The laboratory tested 26,239 COVID-19 PCR patient specimens on the Applied Biosystems 7500 Fast Real Time PCR instruments from April 7, 2020. through June 22, 2020. The laboratory tested 278 COVID-19 IgG antibody patient specimens on the Architect instrument from May 17, 2020 through June 22, 2020. 4. Email correspondence with TS #2 on June 22, at 4:03 PM confirmed the laboratory director failed to ensure verification procedures were adequate before COVID-19 patient testing started on the PCR instrument

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
 Based on the lack of initial training documentation and interview with technical supervisor(TS) #2, the laboratory director failed to ensure four of four testing personnel(TP) received appropriate training prior to testing COVID-19 patient specimens on the Applied Biosystems 7500 Fast Real Time PCR instrumentation. Findings: 1. The laboratory could not provide documentation to show TP #2, 13, 14, 15 received initial training prior to testing COVID-19 specimens on the Applied Biosystems 7500 Fast Real Time PCR instrumentation. 2. Interview with TS # 2 on June 22, 2020 at 11:30 AM confirmed the laboratory director failed to ensure all personnel received appropriate training prior to testing COVID-19 specimens on the PCR instrumentation.