Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0460367	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Group Amc	131 B Cherokee Rose Lane, Covington, LA	

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
D0000	A Certification survey was performed at Gastroenterology Group, AMC-CLIA ID # 19D0460367 on June 13, 2018. Gastroenterology Group, AMC was not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing, Testing Personnel
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following procedure was not included: a) Corrective action to take if equipment temperatures are not within acceptable range 2. In interview on June 13, 2018 at 10:30 am, Personnel 3 stated the laboratory does not have a written policy to address actions to take if equipment temperatures are outside of acceptable range.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform corrective actions when the Microtome water bath failed to be within acceptable range as required by the laboratory. Findings: 1. Review of the laboratory's "Microtome Maintenance Log" revealed the acceptable temperature range of the water bath as 40 degrees Celsius to 50 degrees Celsius. 2. Review of the laboratory's "Microtome Maintenance" logs for 2018 revealed the following thirteen (13) dates with unacceptable temperatures: Water Bath Temperature: February 1, 2018 documented temperature 39 degrees Celsius March 23, 2018 documented temperature 39.9 degrees Celsius March 30, 2018 documented temperature 39.9 degrees Celsius April 10, 2018 documented temperature 39.9 degrees Celsius April 13, 2018 documented temperature 39.9 degrees Celsius April 17, 2018 documented temperature 39.9 degrees Celsius April 20, 2018 documented temperature 39 degrees Celsius May 23, 2018 documented temperature 39 degrees Celsius May 24, 2018 documented temperature 38.8 degrees Celsius May 25, 2018 documented temperature 38.8 degrees Celsius May 29, 2018 documented temperature 38.9 degrees Celsius May 30, 2018 documented temperature 38.9 degrees Celsius May 31, 2018 documented temperature 38.8 degrees Celsius 3. In interview on June 13, 2018 at 10:48 am, Personnel 1 stated the acceptable temperature range for the Microtome is 40 degrees Celsius to 50 degrees Celsius. In further interview, Personnel 3 confirmed the water bath temperature for the identified dates were outside of acceptable range.
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 record review and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6096. 2. The Laboratory Director failed to ensure all personnel had the appropriate education and state licensure for performing high complexity testing. Refer to D6102. 3. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established

	performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
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 record review and interview with personnel, the Laboratory Director failed to ensure all personnel had the appropriate education and state licensure for performing high complexity testing. Findings: 1. The laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow two (2) of three (3) testing personnel to perform high complexity testing. Refer to D6170. 2. The laboratory failed to provide documentation that three (3) of three (3) testing personnel met the educational qualifications for performing high complexity testing. Refer to D6171.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure testing personnel met education and licensure requirements to perform high complexity testing. Findings: 1. The laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory

	Personnel Law"), that would allow two (2) of three (3) testing personnel to perform high complexity testing. Refer to D6170. 2. The laboratory failed to provide documentation that three (3) of three (3) testing personnel met the educational qualifications for performing high complexity testing. Refer to D6171.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have current licenses issued by the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law"), that would allow two (2) of three (3) testing personnel to perform high complexity testing. Findings: 1. Review of the laboratory's personnel records revealed the following personnel previously served as testing personnel: Personnel 4 (terminated December 13, 2017) Personnel 5 (terminated February 2, 2018) 2. Further review of personnel records revealed no documentation of State of Louisiana licenses for Personnel 4 and Personnel 5. 3. In interview on June 13, 2018 at 10:55 am, Personnel 1 stated Personnel 4 and Personnel 5 did not have a State of Louisiana license.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the

	military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation that three (3) of three (3) testing personnel met the educational qualifications for performing high complexity testing. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 currently serves as testing personnel. 2. Review of personnel records revealed the following personnel previously served as testing personnel : Personnel 4 (terminated December 13, 2017) Personnel 5 (terminated February 2, 2018) 3. Review of personnel records for Personnel 2 revealed an Associate of General Studies diploma; however, the laboratory did not provide documentation of her college course transcripts to ensure the minimum educational requirements were met. 4. In interview on June 13, 2018 at 9:45 am, Personnel 2 stated she did not have a copy of her college transcript to show completed science courses. 5. Further review of personnel records revealed the laboratory did not maintain documentation of education for Personnel 4 and Personnel 5. 6. In interview on June 13, 2018 at 10:00 am, Personnel 3 stated the laboratory did not have copies of education for Personnel 4 and Personnel 5.