Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0257137	04/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
George L Smith Iii Md	4166 A Newton Drive, Covington, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 2, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to test the PT samples with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed the laboratory failed to rotate testing personnel (TP) in the examination of PT samples for the following Bacteriology PT events: 2017: Events 2 and 3; 2018 - All 3 events. 2. An interview with the laboratory director in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed TP was not rotated for the aforementioned Bacteriology PT events.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency

	testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all records for a minimum of 2 years as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed there were no PT attestation statements or bacteriology PT log sheets available at the time of survey for the following Bacteriology PT events: 2017 - Events 1 and 2: 2018 - All 3 events. 2..An interview with the laboratory director in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed there were no attestation statements or bacteriology sheets available at the time of survey for the aforementioned PT events.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency as required. Findings include: 1. SOP review revealed the laboratory did not establish and follow a TP competency policy and procedure. 2. An interview with the laboratory director in the clinic lobby on 4/2 /2019 at approximately 1:00 p.m. confirmed there was not a TP competency policy and procedure in the SOP.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to ensure all PT verification activities were documented as required. Findings include: 1. American Academy of Family Physicians PT document review revealed corrective action was not documented for a score of 80 percent for 2018 Bacteriology Event #1. 2. An interview with the LD in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed corrective action was not documented for 2018 Bacteriology Event #1.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. Findings include: 1. SOP review revealed the laboratory did not establish and follow a quality assessment (QA) plan. 2. An interiew with the laboratory director (LD) in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed the SOP did not contain a QA plan.
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 laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to include required policies and procedures when applicable to the test procedure. Findings include: 1. SOP review revealed there was not a policy and procedure for venipuncture. 2. SOP review revealed there was not a policy and procedure for critical laboratory values. 3. SOP review revealed there was not a policy and procedure for corrective action when control results fail to meet the laboratory's criteria for acceptability. 4. SOP review revealed there was not a policy and procedure for sterility checks of bacteriology media. 5. SOP review revealed there was not a policy and procedure to check each batch of bacteriology media for its ability to support or, as appropriate, inhibit growth of specific organisms 4. An interview with the laboratory director in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed the aforementioned required policies and procedures were not included in the SOP.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to cease the use of expired laboratory testing supplies after the expiration date as required. Findings include: 1. Observation during the laboratory tour on 4/2/2019 at approximately 12:00 p.m. revealed the following expired vacutainer tubes were on the counter in the phlebotomy area -- EDTA expired 12/31/2018; Red top tubes expired 3/31/2019. 2. Observation during the laboratory tour on 4/2/2019 at approximately 12:00 p.m. revealed there were no unexpired vacutainer tubes in the laboratory at the time of survey to replace the expired EDTA or the Red top tubes. 2. An interview with Staff #3 (CMS 209) in the laboratory on 4/2/2019 at approximately 12:00 p.m. confirmed expired vacutainer tubes were on the counter in the phlebotomy area . During the same interview, Staff #3 confirmed there were no unexpired EDTA or Red top tubes in the laboratory at the time of survey.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) documents and staff interview, the laboratory failed to perform required quality control (QC) for bacteriology media. Findings include: 1. Bacteriology QC document review revealed the laboratory did not perform and document sterility checks for each batch of Uricheck media for the following dates: 2017 (June - December), 2018, and 2019 thus far. 2. Bacteriology QC document review revealed the laboratory did not check each batch of Uricheck media for its ability to support growth and, as appropriate, select or inhibit growth of specific organisms for the following dates: 2017 (June - December); 2018, and 2019 thus far. 3. An interview with the laboratory director in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed the aforementioned QC was not performed for 2017 (June - December), 2018, and 2019 thus far.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure all PT reports were reviewed by appropriate staff as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD failed to review PT reports for the following Bacteriology events: 2017 - Event 3 and 2018 - Event 2. 2. An interview with the LD in the clinic lobby confirmed the PT reports were not reviewed for the aforementioned PT events.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on policy and procedure manual (SOP) review and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each person engaged in performance of all phases of testing as required. Findings include: 1. SOP review revealed the LD failed to establish a duties and responsibilities policy for the laboratory. 2. An interview with the LD in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed there was not a duties and responsibilities policy in the SOP.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review, proficiency test (PT) document review, testing personnel (TP) document review, quality control (QC) document review, observation, and staff interview, the technical consultant/laboratory director TC/LD) failed to provide technical oversight of the laboratory. Findings include: 1. Review of the SOP, PT, TP, and QC documents, and observation during the laboratory tour revealed the TC/LD failed to provide technical oversight of the

	laboratory. 2. An interview on 4/2/2019 in the clinic lobby with the TC/LD confirmed the failure of the TC/LD to provide technical oversight of the laboratory.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to evaluate and document TP performance annually as required. Findings includle: 1. TP document review revealed the TC/LD did not perform annual competencies for Staff #2 (CMS 209) and Staff #3 (CMS 209) in 2017, 2018, and 2019 thus far. 2. An interview with the TC/LD in the clinic lobby on 4/2/2019 at approximately 1:00 p.m. confirmed annual competencies were not performed for Staff #2 (CMS 209) and Staff #3 (CMS 209) for the aforementioned dates.