Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0932162	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tracy Middlebrooks Jr Md Pc	2315 A Central Avenue, Augusta, 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 September 25, 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:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), observation, and staff interview, the laboratory failed to establish and make accessible safety procedures to ensure protection from chemical, biochemical, and biohazardous materials as required. Findings include: 1. SOP review revealed the lack of an eyewash procedure. 2. Observation during the laboratory area tour revealed there was no eyewash equipment or bottled eyewash. 3. An interview with the laboratory director (LD) in the laboratory area on 9/25/2019 at approximately 2:00 p.m. confirmed there was no eyewash equipment in the office. During the same interview the LD confirmed there was no policy and procedure for eyewash equipment in the SOP.
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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written polices and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems as required. Findings include: 1. SOP review revealed the lack of a quality assurance (QA) policy and procedure. 2. An interview with the laboratory director in the front office on 9/25/2019 at approximately 3:00 p.m. confirmed the lack of a QA policy and procedure. in the SOP.
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 review of the laboratory policy and procedure manual (SOP) the laboratory failed to include required policies and procedures. Findings include: 1. SOP review revealed the lack of a policy and procedure for record retention. 2. An interview with the laboratory director in the front office area on 9/25/2019 at approximately 3:00 p. m. confirmed there was not a record retention policy and procedure in the SOP.
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) the laboratory failed to include required policies and procedures for all phases of laboratory testing.

	Findings include: 1. SOP review revealed the lack of policies and procedures for the following: Specimen storage Corrective action Step-by-step- for urine specimen collection Proficiency testing Sterility checks for bacteriology media 2. An interview with the LD in the front office area on 9/25/2019 at approximately 2:45 p.m. confirmed the lack of the aforementioned polices and procedures in the laboratory SOP.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory maintenance logs and staff interview, the laboratory failed to monitor temperature as required. Findings include: 1. Based upon maintenance log review, the laboratory failed to monitor room temperature (RT), as required by the Strep Select media manufacturer, for the following time periods: 2017 - September through December; 2018, and 2019 thus far. 3. An interview with the laboratory director (LD) in the office area on 9/25/2019 at approximately 3:00 p.m. confirmed the aforementioned lack of RT logs for 2017, 2018, and 2019 thus far.
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 bacteriology quality control (QC) document review and staff interview, the laboratory failed to perform sterility QC for each batch of media as required. Findings include: 1. Strep (Streptococcus) Select bacteriology QC document review revealed there were no incubated sterility checks performed for each new batch of media or each new lot number of media for the following dates: 2017 -- September through December, 2018, and 2019 thus far. 2. An interview with the laboratory director in the front office area on 9/25/2019 at approximately 2:30 p.m. confirmed incubated sterility checks were not performed for Strep Select bacteriology media for the aforementioned time periods.
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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each person involved in all phases of laboratory testing as required. Findings include: 1. SOP review revealed the lack of a a duties and responsibilities policy and procedure. 2. An interview with the LD on 9/25/2019 in the front office area at approximately 2:30 p.m. confirmed there was not a Duties and Responsibilities policy and procedure in the laboratory SOP.