STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	11D0710009	A. BUILDING _____ B. WING _____	09/30/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SUMMIT MEDICAL ASSOCIATES PC	1874 PIEDMONT RD STE 500-E ATLANTA, GA 30324

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D 000	INITIAL COMMENTS A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 30, 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:	D 000		
D5209 510M	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) the laboratory failed to establish a required competency policy for evaluation of testing personnel (TP) performance. Findings include: 1. SOP review revealed the lack of a six-month competency for evaluation of TP. 2. An interview with Staff #5 (CMS 209) in a consultation room on 9/25/2019 at approximately 11:30 a.m. confirmed the lack of the aforementioned policy.	D5209		11/11/19
D5401 510M	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	D5401		10/31/19

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D5401	Continued From page 1 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 for record retention. Findings include: 1. SOP review revealed there laboratory failed to establish a policy and procedure for record retention. 2. An interview with Staff #5 (CMS 209) in a consultation room on 9/30/2019 at approximately 12:00 p.m. confirmed the lack of a record retention policy in the SOP	D5401		
D5403 510M	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.	D5403		10/31/19

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D5403	Continued From page 2 (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 applicable to the test procedure. Findings include: 1. SOP review revealed the lack of policies and procedures for the following: specimen labeling specimen storage specimen processing (including appropriate centrifugation of vacutainer tubes) specimen collection (step-by-step for venipuncture)	D5403		

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D5403	Continued From page 3 2. An interview with Staff #5 (CMS 209) in a consultation room on 9/30/2019 at approximately 12:30 p.m. confirmed the lack of aforementioned policies and procedures in the SOP.	D5403		
D5429 510M	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory maintenance logs, the laboratory failed to perform and document maintenance with frequency required by the manufacturer. Findings include: 1. Review of the laboratory eyewash log revealed required weekly checks were not performed for the following 2019 time periods: March and June -- performed 2 weeks out of 4 weeks; July -- performed 1 week out of 5. 2. An interview with Staff #5 (CMS 209) in a consultation room on 9/30/2019 at approximately 12:30 p.m. confirmed the aforementioned lack of eyewash equipment maintenance.	D5429		10/31/19
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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,	D6004		11/11/19

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D6004	Continued From page 4 and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of testing personnel documents and staff interview, the laboratory director (LD) failed to delegate technical consultant (TC) duties and responsibilities to qualified personnel. Findings include: 1. TP competency document review revealed the annual competencies for -- 2018: Staff #3, Staff #5, and Staff #6 (all on CMS 209) and for 2019: Staff #4 (CMS 209) -- were performed by unqualified personnel due to lack of education qualifications. 2. An interview with Staff #5 (CMS 209) in a consultation room on 9/30/2019 at approximately 12:00 p.m. confirmed the aforementioned annual competencies were performed by unqualified personnel due to lack of education qualifications.	D6004		
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for	D6054		11/11/19

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D6054	Continued From page 5 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 laboratory director/technical consultant (LD/TC) failed to perform required annual competencies on TP. Findings include: 1. TP competency document review revealed an annual competency for moderate complexity testing was not performed for Staff #4 (CMS 209) in 2018. 2. TP competency document review revealed 2018 annual competency documentation for Staff #2(CMS 209)was not available at the time of survey. 2. An interview with Staff #5 (CMS 209) in a consultation room on 9/302019 at approximately 12:00 p.m. confirmed the aforementioned lack of annual TP competency documentation.	D6054		