Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2004711	07/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Square Care Medical Group, Llc	191 Herricks Road, Garden City Park, NY	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of American Proficiency Institute (API) Proficiency Testing (PT) records and confirmed in an interview with the office manager and the testing person, the laboratory failed to retain API PT records and documentation to include signed attestation forms, test result forms, and a signed PT summary reports for the second and third events in 2017 and for the first event in 2018.
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 a lack of policies and procedures and confirmed in an interview with the office manager at the time of the survey, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components to assess testing personnel's competency, semi-annually during the first year of patient testing and at least annually, after the first year.
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 a lack of Quality Assessment (QA) procedures and an interview with the office manager, the laboratory failed to establish and follow a written policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problem that may occur in the laboratory testing. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 30, 2017.
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 a lack of a procedure manual and an interview with the office manager, the laboratory failed to have a written procedure manual available to include policies and procedures for review. Finding: It was confirmed with the office manager on July 16, 2018 at approximately 3:00 PM, that the laboratory failed to have a signed and dated procedure manual available for review.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Control (QC) records and an interview with the office manager and the testing person, the laboratory failed to have a procedure that defines the the BD Affirm VP III microbial identification test analyzer QC process, including the frequency QC material is tested during analyzer operation, criteria for run acceptability, and remedial action to be taken for unacceptable QC. The laboratory failed to perform external QC for the BD Affirm VP III microbial identification test from 4/18/17 through the survey date. . FINDINGS: 1.

	The office manager and the testing person confirmed on July 16, 2018 at approximately 3:00 PM, that the laboratory failed to perform the external control material (Trivalent Swab) from 4/18/17 through the survey date. 2. The laboratory failed to have a procedure that defines the BD Affirm VP III QC process. 3. Approximately 340 patients were tested and reported for Gardnerella, Candida and Trichomonas from 4/18/17 through the survey date. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 30, 2017.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records and an interview with the office manager, the laboratory failed to establish a Risk Assessment (RA) plan as part of the Individual Quality Control Plan (IQCP) for the Affirm VPIII Microbial Identification Test. Findings: The office manager confirmed during the July 16, 2018 onsite survey that the laboratory director failed to establish a Risk Assessment (RA) plan to include all phases of bacteriology, mycology and parasitology testing using the Affirm VPIII microbial identification system, to include potential sources of error for the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 30, 2017.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's findings and confirmed in an interview with the office manager, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the surveys conducted on 1/30/2017; 2. QC program for Affirm testing was maintained, refer to D6020; 3. Laboratory's QA program maintained, refer to D6021; 4. Testing personnel had a six month competency evaluation, refer to D6053; 5. Testing personnel had their annual competency evaluation, refer to D6054. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 30, 2017.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's QC records and an interview with the office manager and the testing person, the laboratory director failed to ensure that the quality control program was maintained to assure quality testing for bacteriology, mycology and parasitology testing. Refer to D5441. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 30, 2017.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of a Quality Assessment (QA) procedure and documentation and an interview with the office manager and the testing person, the laboratory director failed to to establish a written Quality Assessment program for general laboratory systems. Refer to D3037, D5209, D5291, D5401, D5445 PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON JANUARY 30, 2017.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a surveyor review of the personnel records and an interview with the office manager and the laboratory testing person, the laboratory director, acting as the technical consultant, failed to perform and document the semi-annual evaluation for the three of three testing personnel during the first year of patient testing in calendar year 2017. Refer to D5209.

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 a surveyor review of personnel records and an interview with the office manager at the time of the survey, the laboratory director, acting as the technical consultant, failed to perform the annual competency evaluation for the three of three testing personnel who perform moderate complexity Affirm testing in calendar year 2017. Refer to D5209.