Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0923416	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Star Medical Offices Pc	415 Oceanview Avenue, Ground Floor, Brooklyn, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on the laboratory's lack of records of waived testing and an interview with the office manager, the laboratory failed to have records available for waived kits for HIV 1&2, urine drug testing and H-pylori. Findings: It was confirmed by the office manager at approximately 12:00 PM on the date of survey that there were no written procedures nor system for tracking or quality control for the three waived tests performed in the laboratory. Approximately 195 patient samples were tested.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by:

	Based on lack of proficiency testing (PT) records and confirmed in an interview with the office manager at the time of the survey, the laboratory failed to enroll in an approved PT program for IgE immunology testing in the calendar year 2017 and 2018. FINDINGS: The office manager confirmed that while they were enrolled for hsCRP in Immunology, they were not enrolled for the regulated analyte IgE.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of TOSOH AIA-900 instrument tapes and an interview with the testing person, the laboratory had no compilation of quality control (qc) records enabling the surveyor to review qc records for more than a single day. Findings: It was confirmed by the testing person at 11:30 AM on the date of survey that the only way to review qc for all chemistry and endocrinology and immunology was by going through the rolled printouts from the TOSOH analyzer. 1. The laboratory had no system to track and record qc results over time to look for shifts and trends and to ensure results were within acceptable ranges. 2. Surveyor was unable to confirm that the manufacturer's established QC package insert ranges compared with the lot numbers of QC material.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of TOSOH AIA-900 instrument tapes and an interview with the testing person, the laboratory had no compilation of quality control (qc) records enabling the surveyor to review qc records for more than a single day. Findings: 1. It was confirmed by the testing person at 11:30 AM on the date of survey that the only way to review qc for all chemistry and endocrinology and immunology testing was to review each day's rolled printout from the TOSOH analyzer. 2. The laboratory had no system to track and record qc results over time to look for shifts and trends and to ensure results were within acceptable ranges.