Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1083507	10/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Jfk Medical Center Satellite Emergency	1200 Randolph Road, Plainfield, NJ	

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
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 the lack of Quality Control Verification (QCV) records and interview with the General Supervisor (GS), the laboratory failed to verify QC material before use for Lactate tests performed on the Nova Statstrip on the date of survey. The GS confirmed 10/6/22 at 1:15 pm that QC material was not verified before putting in use.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel

	who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Test Report (TR) and interview with the General supervisor (GS), the laboratory failed to maintain an accurate information system for Hematology, Endocrinology and routine Chemistry tests from 2/25/20 to the date of the survey. The findings include: 1. Review of the AL and revealed: a. Three out of eight AL entries had no collection time, date or tests ordered. b. Eight out of eight TR had collection times dates and test results. 2. The GS confirmed at 2:45 pm on 10/6/22 the laboratory did not main an accurate information system.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Test Report (TR) and interview with the General Supervisor (GS)), the laboratory failed to report Covid 19 testing accurately on the date of survey. The finding includes: 1. The laboratory performed COVID 19 non Food and Drug Administration (FDA) cleared tests. 2. A review of three out of three Covid 19 TR revealed that the The FDA COVID EUA statement appeared in the EMR but did not appear on the TR when printed. 3. The GS confirmed on 10/6/22 at 3: 00 pm that COVID 19 tests were not reported accurately. .