Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1083507	03/22/2018
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Performance Specifications (PS) records and interview with the General Supervisor (GS), the laboratory failed to verify accuracy for Human Chorionic Gonadotropin tests performed on the Abbott I-Stat analyzer before reporting patient test results from February 2018 to the date of survey. The GS confirmed on 3/22/18 at 3:30 pm the PS was not done.
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: Based on surveyor review of the Test Report (TR) and interview with the General Supervisor (GS) the laboratory failed to have all the required information on the TR from February 2018 to the date of survey. The findings include: 1. Lactate test did not have a reference range. 2. The name and address of the laboratory performing the test was not on the TR. 3. The GS confirmed on 3/22/18 at 2:35 pm that the TR did not have all the required information.