Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0124262	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jfk Medical Associates	2 Lincoln Highway #501, Edison, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all Testing Personnel (TP) who perform Routine Chemistry Tests participated in the American Association of Bioanalysts (AAB) PT events in the calendar year 2017 to the date of the survey. The finding includes: 1. A review of the PT attestation forms revealed that three of four TP did not perform PT. 2. The TP #1 listed n CMS form 209 confirmed on 6/4/19 at 2:00 pm that PT events were not rotated amongst TP.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel(TP), the laboratory failed to review and evaluate Routine Chemistry PT results obtained from the American Association of Bioanalysts for all events in the calendar year 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 6/4/19 at 1:30 pm that the laboratory did not review and evaluate all PT results.

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 surveyor review of the Procedure Manual and interview with Testing Personnel (TP), the laboratory failed to follow the "Internal Quality Control" procedure for Routine Chemistry test from the calendar year 2017 to the date of survey. The findings include: 1. The PM stated "Package inserts with control expected ranges will be saved with the results", no package inserts were saved. 2. The PM stated "Levy Jennings Charts will be printed and saved", no levy Jennings charts were printed. 3. The PM stated "The Laboratory Director (LD) will review and sign the Quality Control (QC) logs each month". There was no evidence of QC reviewed. 4. The TP #1 listed on CMS form 209 confirmed on 6/4/19 at 1:45 pm that the above mentioned procedures were not followed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have an approved, signed and dated PM by the Laboratory Director (LD) from 2017 to the date of the survey. The TP #4 listed on CMS from 209 confirmed on 6/4/19 at 12:30 pm the LD did not sign the PM.
D5429	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 surveyor review of the Maintenance Record (MR) and interview with the Testing Personnel (TP), the laboratory failed to perform and document monthly maintenance as specified by the manufacturer of the Bio-Rad D-10 analyzer used in Routine Chemistry testing in the calendar year 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 6/4/19 at 2:05 pm that there was no evidence of monthly maintenance as specified by the manufacturer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least once every six months for Routine Chemistry test performed on the Bio-Rad D-10 analyzer from 2017 to the date of the surveyor. The TP #1 listed on CMS for 209 confirmed on 6/1/19 at 2:10 pm CV was not performed every six months.
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 surveyor review of Quality Control (QC) records, Manufacture's Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Routine Chemistry testing performed on the Bio-Rad D-10 analyzer from the calendar year 2017 to the date of survey. The finding includes: 1. The TP was unaware of QC verification. 2. The laboratory did not verify all QC materials used from January 2017

	to the date of survey. 3. The TP #1 Listed on CMS form 209 confirmed on 6/4/2019 at 12:30 pm that QC materials were not verified before put in use.
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 Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to include all the required information on the FR from January 2019 to the date of survey. The finding includes: 1. Ten out of ten FR did not have the laboratory address. 2. The TP #1 listed on CMS from 209 confirmed on 6/4/19 at 2:30 pm the FR did not have all the required information.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for verifying manually entered test results from January 2017 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 6/4/19 at 2:00 pm that the laboratory did not have the procedure mentioned above.