Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0543663	11/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bedford Health Associates	9001 Wilshire Ste 200, Beverly Hills, CA	

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
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 review of the laboratory's policy and procedure (SOP), and interview with the technical consultant the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. The findings included: a. Based on the laboratory's policy and procedure titled "Quality Control Program" stated: "Quality Control and Corrective Actions: Technologist and technicians` are responsible for assuring that quality control tests are performed, and values are in range before releasing patient test values. Control samples are to be tested in the same manner as patient samples. 1.1 Routine Chemistry 1.1.4 Corrective action is performed and document anytime the quality control and or calibration values exceed expected ranges, the instrument malfunction or start up data exceeds acceptable parameters." b. For eight (8) out of eight (8) random patient test results reviewed covering period from 1/25/2017 to 2/5/2019, eight (8) were analyzed and reported. The patient results could have been affected by not following their established policy and procedure regarding laboratory systems requirements. c. The technical consultant confirmed (11/21/ 2019, 13:30) that the laboratory did not follow policy and procedure in the general laboratory system, as stated in their SOP.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. failed to document corrective actions taken when quality control materials failed to meet the criteria for acceptability, including assessment of patient test results (See D5783); and failed to follow written policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems (D5791).
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 review of the laboratory's policy and procedure (SOP), Levy-Jennings charts, and interview with the technical consultant the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. The findings included: a. Review of the laboratory's policy and procedure stated: "Quality Control Program 1. Quality Control and Corrective Actions: 1.1 Routine Chemistry 1.1.2 3-level control is run at the start of each shift." b. Review of the Levy-Jennings indicated that only 2 level of QC materials are being ran at start of each shift. c. For eight (8) out of eight (8) random patient test results reviewed covering period from 1/25/2017 to 2/5/2019, eight (8) were analyzed and reported. The patient results could have been affected by not following their established policy and procedure regarding QC materials number of levels ran. d. The technical consultant confirmed (11/21/ 2019, 13:30) that the laboratory did not follow policy and procedure.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory's Levy -Jennings data, and random patient sampling test results and interview with technical consultant, it was determined that the laboratory failed to follow its own acceptable criteria prior to releasing patients results. The findings included: a. The laboratory failed to review test system criteria for acceptability before reporting patient test results covering period from approximately 10/5/18 to 2/28/19, the following analyte levels were found to be unacceptable. Glucose Level 1 exceeded 3S.D. about 18 times. Sodium Level 1, exceeded 3S.D. about 17 times. Level 2, exceeded 3S.D. about 23 times. Chloride Level 1 exceeded 3S.D. about 5times. Level 2 exceeded 3 S.D.about 5 times. b. For four (4) out of four (4) random patients test results reviewed covering the period from 10/5/18 to 2/28/19. Four (4) patients test results were analyzed and reported prior to corrective action and documentation of erroneous quality control results. c. Technical consultant confirmed on (11/21/19, 13:30) that the laboratory failed to correct and document quality control that was not acceptable prior to releasing patients results.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory Levy -Jennings data, and random patient sampling test results and interview with technical consultant, it was determined that the laboratory failed to take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. See D 5481.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's SOP, Levy -Jennings data, random patient sampling test results and interview with technical consultant, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. See D 5291, D 5441, D 5481.
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 the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that laboratory follow establish quality control, quality assessment procedure, laboratory testing personnel competency evaluation and laboratory oversight. See D6014, D 6020, D 6022, D 6024 and D 6072.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure titled; "Laboratory Competency Assessment "and interviews with the technical consultant it was determined that the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. See D 6072.
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 review of laboratory QC and Levy- Jennings charts, and interview technical consultant, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. See D 5481.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory QC and Levy- Jennings charts, and interview technical consultant, the laboratory director failed to ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. See D 5481 and D 5791.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory QC and Levy- Jennings charts, and interview technical consultant, the laboratory director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. See D 5783 and D 5791.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure titled; "Laboratory Competency Assessment" dated reviewed period from 6/2017 to 6/2018 (RV) and 9 /2018 to 2/2019 (HG), (initial), and interview with the technical consultant the laboratory failed to adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. The findings included: a. The Laboratory Competency Assessment for two (2) testing personnel (RV) and (HG) stated: "Monitoring and Recording of Test Results" Patient results were not reported until met established acceptable criteria The above criteria for both testing personnel were all met." b. Based on review of laboratory Levy -Jennings data, and random patient sampling test results and

	interview with technical consultant, it was determined that the laboratory failed to follow its own acceptable criteria prior to releasing patients results. c. The laboratory failed to review test system criteria for acceptability before reporting patient test results from covering period approximately 10/5/18 to 2/28/19, the following analyte levels were found to be unacceptable. Glucose Level 1 exceeded 3 S.D. about 18 times, Sodium Level 1, exceeded 3 S.D.about 17 times Level 2, exceeded 3 S.D. about 23 times Chloride Level 1 exceeded 3 S.D. about 5times Level 2 exceeded 3 S. D.about 5 times d. For four (4) out of four (4) random patients test results were reviewed covering the period from 10/5/18 to 2/28/19. Four (4) patients test results were analyzed and reported prior to corrective action and documentation of erroneous quality control results. e. Technical consultant confirmed on (11/21/19, 13:30) that the laboratory testing personnel failed to follow established Laboratory Competency Assessment skills.