

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0543663	<b>(X3) Date Survey Completed</b>  11/18/2021
<b>Name of Provider or Supplier</b>  Bedford Health Associates	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the laboratory personnel (LP) and the laboratory director (LD), it was determined that the laboratory failed to enroll in proficiency testing (PT) for most of 2019, all of 2020 and January-September of 2021. The laboratory inspection occurred on 11/18/21 between 11 a.m. and 1 p.m. Findings include: 1.The Casper 096 report for the 2019-2021 was reviewed, and there were no entries for any of the CMS specialties for cycles 1 and 2 of 2019, none for 2020 and none for 2021 for any analytes. 2.The LP indicated that API (American Proficiency Institute) was used for cycle 3 of 2019 for Hematology only. 3.Testing in the 2019-2021 timeframe included: -CBC (to include Cell ID/Diff, Hgb, Hct, WBC and platelets; Sedrate -Chemistry to include: Albumin ALP, ALT and AST BUN Calcium Cholesterol Cholesterol HDL Chloride C02 CPK Creatinine DBili Glucose Glycol HgB Potassium Sodium T3 Uptake Thyroxine TBili Total Protein Triclycerides Uric Acid 4.At approximately 12:00 p.m. on 11/18/21, the LP and LD affirmed that there were no API proficiency reports for the timeframes mentioned above. 5. Hematology proficiency testing for Cycle 3 in 2019 was acceptable. 6. The laboratory is no longer performing general chemistry or hematology testing.</p>

<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the quality control (QC) documentation and associated log sheets, and an interview with the laboratory personnel (LP) and the laboratory director (LD), it was determined that there was not QC documentation for Hematology and Chemistry testing during certain periods of 2020 and 2021. The laboratory inspection occurred on 11/18/21 between 11 a.m. and 1 p.m. Findings include: 1. Quality control documentation was reviewed for Chemistry and Hematology testing (to support instrumentation performance measurement). 2. See D 5447 for supporting detail.</p>
<p><b>D5447</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) documentation and associated log sheets, and an interview with the laboratory personnel (LP) and the laboratory director (LD), it was determined that there was not QC documentation for Hematology and Chemistry testing during certain periods of 2020 and 2021. The laboratory inspection occurred on 11/18/21 between 11 a.m. and 1 p.m. Findings include: 1. Quality control documentation was reviewed for Chemistry and Hematology testing (to support instrumentation performance measurement). 2. Control documentation could not be found for the following timeframes: - 1/1/2020-5/31/2020 - 8/1/2020-12/31/2020 - 1/1/2021-9/30/2021 3. At approximately 12:30 p.m. on 11/18/21, the LP and LD affirmed that there was no QC documentation.</p>
<p><b>D6015</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)</p> <p>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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p>

This STANDARD is not met as evidenced by:

Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the laboratory personnel (LP) and the laboratory director (LD), it was determined that the laboratory failed to enroll in proficiency testing (PT) for most of 2019, all of 2020 and January-September of 2021. The laboratory inspection occurred on 11/18/21 between 11 a.m. and 1 p.m. Findings include: 1. The laboratory director did not ensure that the laboratory was enrolled in an HHS approved proficiency program for each testing cycle defined above. 2. See D 2000.