

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0689349	(X3) Date Survey Completed 11/26/2019
Name of Provider or Supplier Bernalillo Health Care Corp	Street Address, City, State 4500 Montbel Pl Ne, Albuquerque, NM	
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
D0000	<p>During an initial certification survey completed on 11/26/19 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.801 Proficiency Testing Enrollment 42 CFR Part 493.1403 Laboratory Director, moderate complexity 42 CFR Part 493.1413 Technical Consultant An on-site initial survey was scheduled for 10/02/19. During interview on 10/02/19 09:05 am, the Laboratory Director stated the laboratory had just completed the validation studies and had not started testing patients. Based on this information, the laboratory's initial survey was postponed until 11/26/19. Definitions: B-type natriuretic peptide (BNP) measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure. Cardiac Troponin I measurements are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality. Coefficient of Variation is defined as the ratio of the standard deviation to the mean (or its absolute value). The CV is widely used in analytical chemistry to express the precision and repeatability of an assay. The standard deviation (SD) is a measure of the amount of variation or dispersion of a set of values.</p>
D2000	<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>

This CONDITION is not met as evidenced by:
 Based on review of proficiency testing records, emails, and interviews with laboratory staff, the laboratory failed to enroll in proficiency testing for Blood gases (ph and PCO2 or Carbon Dioxide). Findings are: A. During interview on 10/02/19 09:05 am, the Laboratory Director stated the laboratory had just completed the validation studies and had not started testing patients. She also stated that the laboratory had not enrolled in Proficiency Testing. B. During interview on 11/26/19 at 01:30 pm, TC (Technical Consultant) #2 stated the laboratory had submitted the enrollment for API (American Proficiency Institute) and a P.O. (Purchase Order) but did not have enrollment confirmation from the company. C. Review of available proficiency documents on 11/26/19 confirmed the only document available was the enrollment form. D. Review of an email dated 11/27/19 at 09:16 am from API revealed no account with their company using the address or CLIA number. E. Review of an email dated 11/27/19 at 12:16 pm from TC #3 confirmed the laboratory had not enrolled in Proficiency Testing.

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 the review of FDA (Food & Drug Administration) approval letter, manufacturer instructions and validation studies, the laboratory failed to ensure the BNP precision studies met the manufacturer's requirements for accuracy. Findings are: A. Review of the manufacturer's instructions indicated an overall precision or CV of 11.1 % for Level 1 control and 9.8% for Level 3 control. B. Review of FDA 510(k) approval letter K053597 dated 07/21/2006 also indicated an overall precision or CV of 11.1 % for Level 1 control and 9.8% for Level 3 control. C. Review of the laboratory's validation statistics revealed 1 of the 2 i-Stat analyzers (SN 407092) failed to meet the CV requirement provided by the manufacturer. The CV for SN 407092 was 12.0%. D. Review of the "Point of Care New Instrument Studies-BNP" signed by the Laboratory Director on 09/30/19 revealed the laboratory failed to use the correct CV target. 1. The document indicated under comments "CV within 10% for all but Level 1 BNP QC on iStat SN 407092 per validation protocol. CV was 12.0% which is within Manufacturer target CV of 20.0%" 2. There was no documentation indicating the laboratory would repeat the study.

D5447

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(i)(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-- 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.

This STANDARD is not met as evidenced by:
Based on the review of the IQCP (Individualized Quality Control Plan), validation plans, quality control data, emails and interview with TC #2, the laboratory failed to perform studies to support the laboratory's quality control plan for BNP, Troponin, Lactate, and Blood Gases. Findings are: A. During interview on 11/26/19 at 01:14 pm, TC (Technical Consultant) #2 stated external or liquid quality control materials were tested monthly. B. Review of the laboratory's IQCP revealed no documentation of quality control studies that supported a monthly quality control plan including a review of internal controls. 1. Review of the BNP quality control reports indicated test dates of 08/01/19 - 08/12/19, a 12-day period. 2. Review of the Lactate/Blood Gas quality control reports indicated test dates of 08/09/19 - 08/10/19, a 2-day period. 3. Review of the Troponin quality control reports indicated test dates of 07/18/19 - 08/02/19, a 15-day period. 4. Review of the laboratory's validation plan indicated TC #2 would run 2 levels (level 1 and level 3) 10 times each for all analytes over a 2-day period. C. Review of emails from TC #2 and TC #1 dated 11/26/19 provided no additional documentation of quality control studies.

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 review of proficiency testing records, personnel records, IQCP (Individualized Quality Control Plan), quality control data, emails and interviews with laboratory staff, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: A. The Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing for Blood gases. See D6015 B. The Laboratory Director failed to ensure all quality control studies were completed to support the laboratory's quality control plan for BNP, Troponin, Lactate, and Blood Gases. See D6020 C. The Laboratory Director failed to ensure the responsibilities of Technical Consultant were performed by qualified staff. See D6028

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records, emails, and interviews with laboratory staff, the Laboratory Director failed to ensure the laboratory was enrolled in proficiency testing for Blood Gases (ph and PCO2 or Carbon Dioxide). Findings are:

A. During interview on 10/02/19 09:05 am, the Laboratory Director stated the laboratory had just completed the validation studies and had not started testing patients. She also stated that the laboratory had not enrolled in Proficiency Testing. B. During interview on 11/26/19 at 01:30 pm, TC (Technical Consultant) #2 stated the laboratory had submitted the enrollment for API (American Proficiency Institute) and a P.O. (Purchase Order) but did not have enrollment confirmation from the company. C. Review of available proficiency documents on 11/26/19 confirmed the only document available was the enrollment form. D. Review of an email dated 11/27/19 at 09:16 am from API revealed no account with their company using the address or CLIA number. E. Review of an email dated 11/27/19 at 12:16 pm from TC #3 confirmed the laboratory had not enrolled in Proficiency Testing.

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 the review of the IQCP (Individualized Quality Control Plan), quality control data, emails and interview with TC #2, the Laboratory Director failed to ensure all quality control studies were completed to support the laboratory's quality control plan for BNP, Troponin, Lactate, and Blood Gases. Findings are: A. During interview on 11/26/19 at 01:14 pm, TC (Technical Consultant) #2 stated external or liquid quality control materials were tested monthly. B. Review of the laboratory's IQCP revealed no documentation of quality control studies that supported a monthly quality control plan including a review of internal controls. 1. Review of the BNP quality control reports indicated test dates of 08/01/19 - 08/12/19, a 12-day period. 2. Review of the Lactate/Blood Gas quality control reports indicated test dates of 08/09/19 - 08/10/19, a 2-day period. 3. Review of the Troponin quality control reports indicated test dates of 07/18/19 - 08/02/19, a 15-day period. C. Review of emails from TC #2 and TC #1 dated 11/26/19 provided no additional documentation of quality control studies.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on the review of personnel records and interview with the Laboratory Supervisor, the Laboratory Director failed to ensure the responsibilities of Technical Consultant were performed by qualified staff. Findings are: A. Review of personnel files revealed 4 (TP #1, TP #2, TP #6 and TP #9) of 18 (TP #1-18) testing personnel were trained by TP #8 and TP #10. B. Review of the personnel files for TP #8 and TP #10 revealed no documentation of technical consultant qualifications to perform tasks such as training. C. During interview on 11/26/19 at 03:18 pm, the Laboratory Supervisor stated both TP #8 and TP #10 were "Superusers" and permitted to train staff in Emergency Medical procedures. He confirmed there was no "delegation of authority" from the Laboratory Director for laboratory testing.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on the review of FDA (Food & Drug Administration) approval letter, manufacturer instructions, validation studies, proficiency testing records, emails, IQCP (Individualized Quality Control Plan), personnel records, quality control data, and interviews with laboratory staff, the Technical Consultant failed to provide technical oversight of the laboratory. Findings are; A. The Technical Consultant failed to ensure the laboratory was enrolled in proficiency testing for Blood gases. See D6041 B. The Technical Consultant failed to ensure all studies were completed and met manufacturer's specifications. See D6040 C. The Technical Consultant failed to establish a quality control plan for all tests performed on the i-Stat analyzer. See D6042 D. The Technical Consultant failed to train 4 (TP #1, TP #2, TP #6 and TP #9) of 18 (TP #1-18) testing personnel. See D6045

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on the review of FDA (Food & Drug Administration) approval letter, manufacturer instructions and validation studies, the Technical Consultant failed to ensure all studies were completed and met manufacturer's specifications. Findings are: The laboratory failed to ensure the BNP precision studies met the manufacturer's requirements for accuracy. See D5421

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:
 Based on review of proficiency testing records, emails, and interviews with laboratory staff, the Technical Consultant failed to ensure the laboratory was enrolled in proficiency testing for Blood gases (ph and PCO2 or Carbon Dioxide). Findings are:
 A. During interview on 10/02/19 09:05 am, the Laboratory Director stated the laboratory had just completed the validation studies and had not started testing patients. She also stated that the laboratory had not enrolled in Proficiency Testing. B. During interview on 11/26/19 at 01:30 pm, TC (Technical Consultant) #2 stated the laboratory had submitted the enrollment for API (American Proficiency Institute) and a P.O. (Purchase Order) but did not have enrollment confirmation from the company. C. Review of available proficiency documents on 11/26/19 confirmed the only document available was the enrollment form. D. Review of an email dated 11/27/19 at 09:16 am from API revealed no account with their company using the address or CLIA number. E. Review of an email dated 11/27/19 at 12:16 pm from TC #3 confirmed the laboratory had not enrolled in Proficiency Testing.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
 Based on the review of the IQCP (Individualized Quality Control Plan), quality control data, emails and interview with TC #2, the Technical Consultant failed to establish a quality control plan for all tests performed on the i-Stat analyzer. Findings are: A. The laboratory failed to perform studies to support the laboratory's quality control plan for BNP, Troponin, Lactate, and Blood Gases. See D5447 B. Review of emails from TC #2 dated 11/26/19 revealed no additional documentation.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
 Based on the review of personnel records and interview with the Laboratory Supervisor, the Technical Consultant failed to train 4 (TP #1, TP #2, TP #6 and TP #9) of 18 (TP #1-18) testing personnel. Findings are: A. Review of personnel files revealed 4 (TP #1, TP #2, TP #6 and TP #9) of 18 (TP #1-18) testing personnel were trained by TP #8 and TP #10. B. Review of the personnel files for TP #8 and TP #10 revealed no documentation of technical consultant qualifications to perform tasks such as training. C. During interview on 11/26/19 at 03:18 pm, the Laboratory Supervisor

stated that both TP #8 and TP #10 were "Superusers" and permitted to train staff in Emergency Medical procedures. He confirmed there was no "delegation of authority" from the Laboratory Director for laboratory testing.