Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537422	02/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Bca Medical Assoc	813 N Washington, Roswell, 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	During a recertification survey completed on 02/26/2020 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.1403 Laboratory Director, Moderate Complexity 42 CFR Part 493.1441 Laboratory Director, High Complexity
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 the review of 2018-2019 proficiency testing records and personnel records, observation, and interview with the laboratory supervisor (TP #1), the laboratory failed to ensure White Blood Cell manual differentials were handled in the same manner as patient samples. Findings are: A. Review 2018-2019 proficiency testing records revealed no documentation of the individual reviewing and reporting results for the White Blood Cell manual differential. The cover page/attestation sheet only has the signatures of all of the testing personnel. B. Observation of TP#2 on 02/26 /2020 at 11:18 am revealed he performed manual differentials without assistance from the laboratory supervisor. C. Review of the personnel files for TP#2 and TP#3 indicated both had been trained by the laboratory supervisor to perform manual differentials. D. During interview on 02/26/2020 at 3:17 pm, the laboratory supervisor stated the photomicrographs used for manual differentials are reviewed together (laboratory supervisor, TP#2 and TP#3) since TP#2 and TP#3 "don't always know some of the answers."
D2020	BACTERIOLOGY CFR(s): 493.823(a)

	Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on the review of 2018-2019 proficiency testing records, CMS (Centers for Medicare & Medicaid Services) Reports and interview with the laboratory supervisor, the laboratory failed to perform and document corrective actions for the proficiency testing failure for the 3rd event of 2018, Bacteriology. Findings are: A. Review of the CMS CASPER Report 96, Facility Profile, indicated the laboratory received a score of 77% for the 3rd event of 2018, bacteriology. B. Review of the laboratory's 2018-2019 proficiency testing records indicated no records related to the failure including any corrective actions. The laboratory supervisor called the proficiency agency for a copy of the results 02/26/2020 at 09:00 am. C. During interview on 02/26/2020 at 9:27 am, the laboratory supervisor stated she did not see the results for the 3rd event of 2018 so she did not perform any corrective actions.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies, personnel records and interview with the laboratory supervisor, the laboratory failed to have written policies for assessing competency of laboratory personnel. Findings are: A. Review of personnel records revealed: 1. No documentation of competency in for all moderate complexity tests performed for 2 of 2 ((TP#2 and TP#3) testing personnel with competency assessments in 2019. See D6030 2. No documentation of competency in 2019 for TP#1 for urine cultures (high complexity). See D6103 3. No documentation of competancy for 2 (TP#1, TP#4) of 4 (TP#1-TP#4) moderate complexity testing personnel. See D6030 4. Competency assessment did not document the method of assessment such as blind sample testing, observation or record review for 2 of 2 ((TP#2 and TP#3) testing personnel with competency assessments for 2019. B. Review of laboratory policies revealed no policy for assessing competency. C. During interview on 02/26/2020 at 02:09 pm, the laboratory supervisor (TP#1) stated the laboratory never had written policies for personnel competency.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on the review of 2019-January 2020 temperature logs, and interview with the Laboratory Supervisor, the laboratory failed to maintain Refrigerator #1 at 2-8 degrees Celsius as required by the manufacturer of the Remel culture media. Findings are: A. Review of the temperature log revealed no documentation of corrective actions when the temperature was greater than 8 degrees Celsius. 1. November 2019 6 of 22 days 11 /06 = 8.3 11/07 = 9.3 11/14 = 8.1 11/19 = 9.0 11/20 = 9.5 11/21 = 9.5 2. December 2019 8 of 20 days 12/12 = 8.9 12/13 = 8.4 12/14 = 8.4 12/17 = 8.5 12/18 = 8.2 12/19 = 8.2 12/26 = 8.6 12/27 = 8.7 3. January 2020 10 of 20 days 01/07 = 8.3 01/08 = 8.5 01/10 = 8.2 01/11 = 8.2 01/13 = 8.1 01/14 = 8.3 01/15 = 8.5 01/16 = 8.8 01/17 = 8.6 01 /31 = 8.1 4. February 2020 9 of 18 days 02/01 = 8.8 02/04 = 8.9 02/07 = 8.2 02/08 = 8.1 02/19 = 8.3 02/20 = 8.1 02/21 = 8.6 02/25 = 9.8 (a downward arrow was documented but the laboratory failed to recheck the temperature after adjusting the refrigerator setting) 02/26 = 8.2 B. Review of the label for the Remel Chocolate agar indicated the media must be stored at 2-8 degrees Celsius. C. During interview on 02 /26/2020 at 10:30 am, the Laboratory Supervisor confirmed this finding.
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 2019-2020 temperature records, personnel records, 2018-2019 proficiency records and interview with the Laboratory Supervisor, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: A. The Laboratory Director failed to ensure proficiency samples were tested in the same manner as patient samples. See D6016 B. The Laboratory Director failed to ensure the laboratory followed written policies for assessing competency of testing personnel. See D6030
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the review of 2018-2019 proficiency testing records and personnel records, observation, and interview with the Laboratory Supervisor (TO #1), the Laboratory Director failed to ensure proficiency samples were tested in the same manner as patient samples. Findings are: The laboratory failed to ensure White Blood Cell manual differentials were handled in the same manner as patient samples. See D2007

D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory policies, personnel records and interview with the laboratory supervisor, the Laboratory Director failed to ensure the laboratory followed written policies for assessing competency of testing personnel. Findings are: A. Review of personnel records revealed: 1. No documentation of competency for 2 (TP#1, TP#4) of 4 (TP#1-TP#4) moderate complexity testing personnel in 2019. 2. No documentation of competency for all moderate complexity tests performed for 2 of 2 ((TP#2 and TP#3) testing personnel. TP#2 had no documentation of bilirubin in 2019 and TO#3 had no documentation for manual differentials in 2018. 3. No documentation of the method of assessment such as blind sample testing, observation or record review for 2 of 2 ((TP#2 and TP#3) testing personnel with competency assessments for 2019. B. Review of laboratory policies revealed no policy for assessing competency. C. During interview on 02/26/2020 at 11:55 am, the Laboratory Supervisor stated that TP#4 doesn't work in the laboratory very often. D. During interview on 02/26/2020 at 02:09 pm, the Laboratory Supervisor stated the laboratory never had written policies for personnel competency.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the review of 2018 proficiency testing records, observation, review of laboratory policies, personnel records, manufacturer instructions, codebook, and interview with the Laboratory Supervisor, the Laboratory Director failed to provide overall direction and management of the laboratory. Findings are: A. The Laboratory Director failed to ensure the test methodology for bacterial identification and susceptibility, BD BBLCRYSTAL Identification Systems Enteric/Nonfermenter ID Kit, was updated to reflect current industry standards. See D6082 B. The Laboratory Director failed to ensure the laboratory followed written policies for assessing competency of laboratory personnel. See D6103
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)

	The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on the review of 2018 proficiency testing records, manufacturer instructions, codebook, and interview with the Laboratory Supervisor, the Laboratory Director failed to ensure the test methodology for bacterial identification and susceptibility, BD BBLCRYSTAL Identification Systems Enteric/Nonfermenter ID Kit, was updated to reflect current industry standards. The laboratory reported performing 491 bacterial culture and sensitivities in a 12 month period. Findings are: A. Review of 2018 microbiology test records indicated the laboratory had received a failing score for bacterial identification. The proficiency agency, MLE or Medical Laboratory Evaluation, indicated the correct answer was Pantoea agglomerans and Corynebacterium species for sample UC - 12 but the laboratory reported Klebsiella species. There was no corrective actions performed for this failure. See D2020 B. Review of the manufacturer's instructions, dated January 2015, indicated the following: 1. "Calculation of BD BBL Crystal Profile Number: Each test result that is scored positive is given a value of 4, 2, or 1, corresponding to the row where the test is located. A value of 0 (zero) is given to any negative result. The numbers (values) resulting from each positive reaction in each column are then added together. A 10-digit number is generated; this is the profile number." 2. The resulting profile number and off-line test results (indole and oxidase) should be entered on a PC in which the BD BBL Crystal ID System Electronic Codebook has been installed, to obtain the identification. A manual codebook is also available. If a PC is not available contact BD Technical Services for assistance with the identification. If using the BD BBL Crystal AutoReader, organisms are automatically identified by the PC." 3. The instructions also indicated, in the list of organisms, the kit had the capability of identifying Pantoea agglomerans, previously known as Enterobactor agglomerans. C. Review of the laboratory's BBL Crystal ID Codebook revealed the codebook did not contain the current name of Pantoea agglomerans, only Enterobactor agglomerans. D. During interview on 02/26/2020 at 10:01 am, the laboratory supervisor stated she was not sure how old her Crystal ID reference book (codebook) was because it was in the laboratory when she started working there 21 years ago. She also stated she had difficulty interpreting the results for sample UC - 12 and read the color changes 3 different times before reporting Klebsiella species.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on observation, review of laboratory policies, personnel records and interview with the Laboratory Supervisor, the Laboratory Director failed to ensure the laboratory followed written policies for assessing competency of laboratory personnel.

	Findings are: A. Review of personnel records revealed no documentation of competency in 2019 for all tests performed for 1 of 1 (TP#1) testing personnel performing urine cultures (high complexity). B. Review of laboratory policies revealed no policy for assessing competency. C. During interview on 02/26/2020 at 02:09 pm, the Laboratory Supervisor (TP#1) stated the laboratory never had written policies for personnel competency.