Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537422	09/24/2024
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	An onsite recertification survey conducted on Septemeber 24, 2024, at BCA Medical Associates found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts Medical Laboratory Evaluation (AAB -MLE) proficiency testing (PT) records and interview with the laboratory supervisor, the laboratory director failed to sign proficiency testing attestation forms verify PT samples were integrated as part of the laboratory's normal patient work flow for two of three testing events for all analytes tested in 2024. Findings included: 1. Review of AAB -MLE proficiency testing records revealed the following attestations unsigned by the laboratory director or designee: - Event 1 Neonatal / Direct Bilirubin; NB Culture ID, Throat; TC Hematology with 3-Part Diff; HD -Event 2 Neonatal / Direct Bilirubin; NB Culture ID, Throat; TC Hematology with 3-Part Diff; HD 2. Interview on 09/24/2024 at 09:40 am with the laboratory supervisor confirmed the above findings. 3. Laboratory reported performing 6,234 moderate complexity tests annually.
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 review of laboratory procedures, BCA Laboratory Disk QC Sheet, and interview with the laboratory supervisor, the laboratory failed to follow their own written procedures for performing quality control (QC) for new lots of Bacitracin disks (A disks) used for throat cultures in September of 2024. Finding included: 1. Review of the laboratory procedure titled "Microbiology Protocol", listed the following requirements for perform QC on A disks: Weekly: A disk (New lot ONLY) = Streptococcus pyogenes 19615, Positive; Streptococcus agalactiae 13813, Negative 2. Review of BCA Laboratory Disk QC Sheet for September 2024 revealed QC done on a new lot of A disks (lot: 6110068) only used Streptococcus pyogenes 19615 positive control, and did not include Streptococcus agalactiae 13813, negative control. 3. Interview on 09/24/2024 at 10:40 am with the laboratory supervisor confirmed the above findings 4. Laboratory reported performing 5,907 throat cultures annually.
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 review of the laboratory's test menu, bilirubin calibration log, and interview with the laboratory manager, the laboratory failed to include 3 levels of calibration controls when performing calibration verification for the Lecia Unistat Bilirubinometer every 6 months in 2023 and 2024 Findings included: 1. Review of the laboratory's test menu revealed the laboratory performed neonatal bilirubin testing on the Lecia Unistat Bilirubinometer (SN#: 222065) 2. Review of the Bilirubin Calibration Log reveal that facility was only running 2 levels of calibration controls, a low level and high level, as part of their calibration verifications for 2023 and 2024. 3. In an Interview on 09/24/2024 at 11:30 am with the laboratory supervisor, they stated the calibration controls they are currently using do come with 3 levels, however they

	are currently only using the 2, confirming the above findings. 4. Laboratory reported performing 50 neonatal bilirubins annually.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Centers of Medicare and Medicaid personnel form (CMS - 209 form), competency assessment records, education records, and interview with the laboratory supervisor, the technical consultant failed to assess competencies for two of three testing personnel (TP) performing moderate complexity testing in 2023 and 2024. Findings included: 1. Review of the CMS - 209 form listed three testing personnel performing moderate complexity testing. CMS - 209 form also listed the laboratory director as being the technical consultant. 2. Review of the laboratory's competency records revealed annual competency assessment for TP 2 and TP 3 in 2023 and 2024 were evaluated by TP 1. 3. Review of education records revealed TP 1 did not meet the education requirements to be a technical consultant and was not qualified to perform competency assessments. 3. Interview on 09/24/2024 at 09:20 am, with the laboratory supervisor confirmed the above findings. 4. Laboratory reported performing 6,234 moderate complexity tests annually.