Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537422	11/18/2022
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	Based upon the onsite recertification survey conducted on 11/18/2022, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 42 CFR Part 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, review of the daily temperature log and interview with staff, the laboratory failed to define the temperature for refrigerator (#2) in which reagents were stored for 2020, 2021 and for 11 of 12 months in 2022. Findings included: 1. Review of the laboratory's daily temperature log titled "Daily Log: Temperatures", for 2020, 2021 and 2022, revealed that the laboratory failed to define an acceptable range, according to manufacturer's instructions, for Refrigerator #2. The log had the following defined range: 2C +/- 8C 2. During a tour of the laboratory on 11/16/2022 at 7:00am, the following test cartridges and reagents were observed in refrigerator #2, located in the main laboratory: Abbott Cholesteph LDX Lipid Profile cassettes, Lot# 431895, Expiration 4/30/2023-10 boxes. Lot# 431896, Expiration 4/30/2023 - 5 boxes. Abbott Cholestech LDX Lipid Profile and Glucose cassettes, Lot# 431903, Expiration 4/30/2023 - 5 boxes. Abbott Cholestech LDX Multianalyte Control, Lot# 902948068, Expiration 6/14/2023-2 boxes. Abbott Afinion HbA1c test cartridges, Lot# 10218043, Expiration 7/03/2023 - 3 boxes. McKesson (Consult Diagnostics) Liquid Urine Controls, Lot# UCL2050009, Expiration 5/12/2024-1 box. Lot# UCL2090010, Expiration 7/15/2024-1 box ESR-Chex bi-level ESR control, Lot# 214104, Expiration 6/27/2023-1 box.

	Lot# 201381, Expiration 1/10/2023-1 box. 3. Review of the manufacturer's instructions and the laboratory's daily temperature log titled "Daily Log: Temperatures", for 2020, 2021 and 2022, revealed that the laboratory failed to define an acceptable defined range, according to manufacturer's requirements. The temperature did not align with the manufacturer's storage requirement for all the reagents, test kits, and cartridges listed below. Abbott Cholesteph LDX Lipid Profile - temperature storage requirement on packaged box was 2-8C (36-46F). Abbott Cholestech LDX Lipid Profile and Glucose - Manufacturer's temperature storage requirement on packaged box was 2-8C (36-46F). Abbott Cholestech LDX Multianalyte Control - Manufacturer's temperature storage requirement on packaged box was 2-8C (36-46F). Abbott Afinion HbA1c test cartridges - Manufacturer's temperature storage requirement on packaged box was 2-8C (36-46F). McKesson (Consult Diagnostics) Liquid Urine Controls - Manufacturer's temperature storage requirement on packaged box was 2-8C (36-46F). ESR-Chex bi-level ESR control - Manufacturer's temperature storage requirement on packaged box was 2-10C (36-48F). 4. During an interview on 11/16/2022 at 12:00 pm, the lead testing person (TP#2) confirmed the above findings.
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 direct observation, review of the policies/procedures, manufacturer's instructions, Gram stain QC log, and an interview with lead testing person, the laboratory failed to provide a written procedure for the in-use BBL Gram Stain Kit. Findings included: 1. Tour of the laboratory on 11/16/22 at 2:30 pm, revealed an in-use BBL Gram Stain Kit by Becton Dickinson, Lot# 210342, expiration date of 1/31/2023. 2. Review of the policies/procedures revealed the laboratory did not have a current procedure for the in-use "BBL Gram Stain Kit". 3. The manufacturer's instructions stated: "Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidance and CLIA regulations for appropriate Quality Control practices .....Run controls using BBL Gram Slide (Cat. No. 231401) or 18-24 h cultures of known gram-positive and gram-negative microorganisms. The following test strains are recommended; Staphylococcus aureus - ATCC 25923 - Expected Results = gram-positive cocci Escherichia coli - ATCC 25922 - Expected Results = gram-negative rods". 4. Review of the Gram Stain QC log revealed no documentation of the microorganism and/or the strain number used for performing quality control with the reported QC result. 5. During interview on 11/16/2022 at 2:30 pm, the lead testing person (TP#2) confirmed the above findings.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

	This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policies/procedures and staff interview, the laboratory failed to ensure that the written procedures included the date of discontinuance for 2 of 2 specialties (Hematology and Microbiology). Findings included: 1. During a tour of the laboratory on 11/16/2022 at 2:13 pm the following was observed; Three containers containing solutions used for the staining of CBC slides requiring manual differentials. The three containers did not have an identifying name of the solution, a lot number, or an expiration date. One BD BBL Gram Stain Kit, Lot# 1207385, Expiration date 1/31/2023, currently being used for Microbiology gram stains. 2. Review of the in-use binder revealed the following outdated policies /procedures; One gram stain procedures: titled "Gram Stain Procedure". No discontinuance date noted on the procedure. This procedure was different than the current in-use BD BBL Gram Stain Kit. One CBC Differential staining kit procedure titled Hematological staining using protocol Hema-3 staining set". The lead TP#2 stated that the procedure was discontinued around August of 2021. No discontinuance date noted on the procedure. One procedure titled "BBL Crystal-ID system", used for identification of microorganisms in Microbiology. No discontinuance date noted on the procedure. 3. During an interview on 11/16/2022 at 5:00 pm, the lead testing person (TP#2) confirmed the above findings.
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 direct observation, review of the manufacturer's instructions, daily temperature logs and interview with staff, the laboratory failed to define the temperature of two refrigerators (#1 & #2) and for the freezer in which reagents were stored for 2020, 2021 and for 11 of 12 months in 2022. Findings included: 1. During a tour of the laboratory on 11/16/2022 at 7:00am the following was observed; Refrigerator #1, located in Microbiology room, had 5 different types of media/agar stored in it; MacConkey Agar - 9 boxes (10 plates each box), Lot# 571129, Expiration date 1/06/2023. SXT Blood Agar - 5 boxes (15 plates each box), Lot# 575372, Expiration date 12/19/2022. Sheep Blood Agar - 11 boxes (10 plates in each box), Lot# 571109, Expiration date 12/29/2022. Mueller Hinton Agar - 10 plates, Lot# 557143, Expiration date 12/15/2022. Chocolate Agar - 2 boxes (10 plates in each box), Lot# 578526, Expiration date 1/17/2023. Refrigerator #2, located in main laboratory, had the following controls stored in it; Cell-Dyne 18 Plus Controls - 1 package (4 sets of Low, Normal, High controls in each package), Lot# 2234, Expiration date 12/09/2022. 3 packages, Lot# 2290, Expiration date 2/3/2023. Freezer, located in the main laboratory, had the following antimicrobial susceptibility /sensitivity disks stored in it; A. Antimicrobial susceptibility/sensitivity disks manufactured by Oxoid; Bacitracin Disks - Lot# 3517374, Expiration 7/2023 - 2

	boxes and 5 cartridges of 50 discs. Erythromycin - Lot# 293116,2 Expiration 2/09 /2023 Suphamethoxazole/Trimethoprim - Lot# 3506525, Expiration 6/30/2025 - 1 box Ciprofloxacin - Lot# 3517263, Expiration 7/04/2025 - 1 box Ceftraiaxone - 2 lot numbers- lot#3517236, Expiration 7/9/25 and lot# 2923793, Expiration 1/28/2023 - 1 box of each lot. Clindamycin - Lot# 3474026, Expiration 4/20/2025 - 1 box Vancomycin - Lot# 2901262, Expiration 1/09/2023 - 1 box Oxacillin - Lot# 3315569, Expiration 6/21/2024 - 1 box Ceftazidime - Lot 3454924, Expiration 3/14/2023 - 1 box Ceftraiaxone - Lot 2923793, Expiration 1/28/2023 - 1 box B. Antimicrobial susceptibility/sensitivity disks manufactured by Becton Dickenson (BD BBL Sensi-Disc); Ciprofloxacin - Lot# 9304779, Expiration 11/30/2022 Ceftraiaxone - Lot# 9304766, Expiration 11/30/2022 Suphamethoxazole/Trimethoprim, Lot# 9323228, Expiration 11/30/2022 Nitrofurantoin - Lot# 9046600, Expiration 3/31/2023 Gentamicin - Lot# 9261928, Expiration 9/30/2023 Tobramycin - Lot# 9365376, Expiration 1/31/2023 2. Review of the manufacturer's instructions and the laboratory's daily temperature log titled "Daily Log: Temperatures", for 2020, 2021 and 2022, revealed that the laboratory failed to define an acceptable range, according to manufacturer's requirements. The temperature log had a range of 2C +/- 8C for the two refrigerators and a range of -20/-8C for the freezer. These ranges did not align with the manufacturer's storage requirement for all the reagents, media, and antimicrobial sensitivity disks listed below. Review of the manufacturer's instructions revealed the following temperature storage requirements: MacConkey Agar - Manufacturer's temperature storage requirement on packaged box was 2-8C. SXT Blood Agar - Manufacturer's temperature storage requirement on packaged box was 2-8C. Sheep Blood Agar - Manufacturer's temperature storage requirement on packaged box was 2-8C. Mueller Hinton Agar - Manufacturer's temperature storage requirement on packaged box was 2-8C. Chocolate Agar - Manufacturer's temperature storage requirement on packaged box was 2-8C. Cell-Dyne 18 Plus Controls - Manufacturer's temperature storage requirement is 2- 10C. All sensitivity discs stored in the freezer, manufactured by Oxoid and by Becton Dickenson, have a manufacturer's storage requirement of -20 to 8C. 3. During an interview on 11/16/2022 at 5:00 pm, the lead testing person (TP#2) confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and an interview with TP#2, the laboratory failed to have a system in place to ensure documentation of lot numbers, preparation/expiration dates for 6 of 6 Quality Control stock micro-organisms and for 3 of 3 reagents used for the staining of CBC (Complete Blood Count) slides requiring manual differentials. Findings included: 1. During a tour of the laboratory on 11/16/2022 at 2:00 pm, the following was observed: A. Plates inoculated with working cultures were observed in the microbiology incubator. The plates were labeled with the name of the stock micro-organism and the ATCC numbers. The microbiology working cultures were not labeled with the Lot # and expiration dates. The following organisms were sub-cultured on MacConkey Agar: E. Coli, ATCC 25922 Proteus Vulgaris, ATCC 13315

	Pseudomonas Aeruginosa, ATCC 27853 The following organisms were sub-cultured on Blood Agar: Streptococcus Pyogenes, ATCC 19615 Streptococcus Agalactiae, ATCC 13813 Staphylococcus Aureus, ATCC 25922 The following organisms were sub-cultured on SXT Blood Agar: Streptococcus Pyogenes, ATCC 19615 Streptococcus Agalactiae, ATCC 13813 Staphylococcus Aureus, ATCC 25922 B. Three containers containing solutions used for the staining of CBC slides requiring manual differentials. The three containers did not have an identifying name of the solution, a lot number, or an expiration date. 2. During interview on 11/17/22 at 5:00 pm, lead testing person (TP#2) stated that the quality control stock micro-organisms and three reagents used to stain the CBC slides requiring a manual differential were obtained from the laboratory of a neighboring hospital and confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control policies/procedures, Media receipt logs for 2020, 2021, 2022, and interview with the lead testing person, the laboratory failed to test each batch, lot, and shipment for positive and negative reactivity for 4 of 4 tests in microbiology. Findings included: 1. Review of the laboratory's quality control policies/procedures revealed the following multiple written procedures for Catalase, Oxidase, and for disk sensitivities. A. Procedure titled "Catalase Test" stated the following: "QUALITY CONTROL: Positive control - Staphylococcus aureus Negative control - Streptococcus pyogenes QC done each day of testing, Log results on QC log sheet." Procedure titled "Microbiology Quality Control" stated the following: "CATALASE TEST: The catalase test is used to differentiate the Staphylococcus species from the Streptococcus species. Positive and negative controls will be performed each day of use." B. Procedure titled "Microbiology Quality Control" stated the following: "OXIDASE TEST: The Oxidase test is used when identifying enteric/nonfermenting organisms. This will be each day of use. Using Pseudomonas aeruginosa as a positive (+) control, E.Coli as a negative (-) control." C. Procedure titled "Sensitivity Quality Control Procedure" stated the following: "To be confident that the sensitivities read are accurate, quality control measures need to be taken. To accomplish this goal, the sensitivity disks used need to be tested with stock cultures of known Susceptibility values. For gram negative organisms E. coli (25922) is used. For gram positive organisms Staphylococcus aureus (25923) ....The controls are to be set up and incubated with the patient sensitivities." Procedure titled "Sensitivities" stated the following: "QUALITY CONTROL; Stock cultures of gram-positive and gram-negative organisms which have an established zone size are tested each day of testing and the results logged on to the appropriate log sheets." Procedure titled "Microbiology Quality Control", stated the following for performing QC on antimicrobial susceptibility disks: "Due to the variability inherent when working with viable organisms, quality control measurements must be taken. Methods of checking

	the validity of testing microbiology include the use of stock cultures with predictable and dependable results. By knowing what reactions will occur with a given stock culture, quality control can be effectively used ..... WEEKLY A disk (new lot only) Streptococcus pyogenes 19615 positive Streptococcus agalactiae 13813 negative" The laboratory failed to perform, document, and follow written procedures regarding quality control for the Catalase, Oxidase, Spot Indole, and for the antimicrobial susceptibility/sensitivity disks. 2. Review of the Media receipt logs revealed the laboratory failed to document the receipt date of each lot number/shipment, and the date when the quality control was performed for the following: Catalase - Quality control demonstrating positive and negative reactivity was not documented. Oxidase - "Bactidrop Oxidase", Lot# 303116, Expiration 3/8/2023. Spot Indole - Lot# 334893, Expiration 1/19/2023. Oxoid Antimicrobial Susceptibility Discs: Bacitracin disk, Lot # 3517374, Expiration date 7/2023. Erythromycin, Lot # 2931162, Expiration date 2 /09/23. Sulfamethoxazole/Trimethoprim, Lot # 3506525, Expiration date 6/30/25. Ciprofloxacin, Lot # 3517263, Expiration date 7/04/25. Ceftriaxone, Lot # 2923793, Expiration date 1/28/23. Ceftriaxone, Lot # 3517236, Expiration date 7/09/25. Clindamycin, Lot #3474026, Expiration date 4/20/25. Vancomycin, Lot #2901262, Expiration date 1/09/23. Oxacillin, Lot # 3315569, Expiration date 6/21/24. Ceftazidime, Lot # 3454924, Expiration date 3/14/23. BD BBL Sensi-Discs: Ciprofloxacin, Lot # 9304779, Expiration date 11/30/22. Ceftriaxone, Lot # 9304766, Expiration date 11/30/22. Sulfamethoxazole/Trimethoprim, Lot # 9323228, Expiration date 11/30/22. Nitrofurantoin, Lot # 9046600, Expiration date 3/31/23. Gentamicin, Lot # 9261928, Expiration date 9/30/23. Tobramycin, Lot# 9365376, Expiration date 1 /31/23. 3. During interview on 11/16/2022 at 11:19 am, the lead testing person confirmed the above findings.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Media Quality Control (QC) logs, laboratory's written policy, and interview with laboratory staff, the laboratory failed to check each batch of media for its ability to support growth and demonstrate selectivity and/or inhibition and its ability to produce a biochemical response before or concurrent with its initial use for 5 of 5 media types and 1 of 1 culture broth from 2020 to November 15, 2022. Findings included: 1. Review of the Media QC Logs (2020 to 2022) revealed the following in use media were not checked for its ability to support growth and/or demonstrate selectivity and/or inhibition and/or its ability to produce a biochemical response. a. MacConkey Agar- Lot 571129, expiration date 1/6/2023, 9 boxes (15 plates in each box), received date 11/08/2022. There was no documentation for ability to support growth, demonstrate selectivity/inhibition, and its ability to produce a biochemical response (pigmentation). b. SXT/Blood Agar- Lot 575372, expiration date 12/19 /2022, 5 boxes (15 plates in each box). Receipt date was not documented on log. There was no documentation for ability to support growth, demonstrate selectivity

	/inhibition, and its ability to produce a biochemical response (hemolytic reaction). c. Blood Agar- Lot 571109, expiration date 12/29/2022, 11 boxes (10 plates in each box), received date 11/08/2022. There was no documentation for ability to support growth and its ability to produce a biochemical response (hemolytic reaction). d. Mueller Hinton Agar- Lot 557143, expiration date 12/15/2022, 10 plates. Receipt date was not documented on log. There was no documentation for ability to demonstrate the quantitative susceptibility to antibiotic sensitivity discs when testing isolates of a staphylococcus spp. e. Chocolate Agar- Lot 578526, expiration date 1/17/2023, 2 boxes (10 plated in each box). Receipt date was not documented on log. There was no documentation for ability to support growth. f. Tryptic Soy Broth- Lot# 536287, expiration date 8/08/2023, 2 boxes (20 each box), received dated 08/31/2022. There was no documentation for ability to support growth. 2. Review of the facility's written policy/procedure titled "Microbiology Quality Control" written in 2020 stated the following: "Media plates must be checked for hydration, sterility, and reference cultures should be used to check the media for the ability to grow the appropriate micro-organisms .....Reference organisms are used as controls for cultures and should be maintained and sub-cultured weekly to different types of media used in the lab ..... A plate from each new batch of culture plates should be tested with the appropriate reference organism to show the media supports, selects, or inhibits bacterial growth or has the biochemical reactivity that is expected." The laboratory failed to follow their written Quality Control (QC) procedure and did not have documentation of performing QC on the media listed in their policy (Mueller-Hinton Agar and Chocolate Agar). The QC policy did not reference MacConkey Agar, SXT/Blood Agar, Blood Agar, or the Tryptic Soy Broth, which are also used by the facility. 3. During interview on 11/17/2022 at 9:00 am, the lead testing person stated that the media is only checked for sterility.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of personnel records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, laboratory policies, training, and competency records for 2021 and 2022, the technical consultant failed to ensure that all laboratory testing personnel were evaluated for competency at least twice during the 1st year of patient testing for 1 (TP#4) of 5 testing personnel. Findings included: 1. Review of personnel records revealed that TP#4 was hired on November 8, 2021. 2. Review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209 signed by the Laboratory Director on 11/15/2022 indicated that TP #4 performed moderate complexity testing. 3. Review of laboratory policies revealed that the laboratory did not have a written policy/procedure for competency assessments. 4. Review of training and competency records provided revealed that testing person #4 was trained in performing moderate complexity testing from November 2021 to April 2022. No documentation for the semi-annual competency was provided for TP#4 for 2022.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the review of personnel records, CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, laboratory policies, training, and competency records for 2021, the technical consultant failed to ensure that annual technical competency evaluations were performed at least annually for 1 (TP# 2) of 5 testing personnel. Findings included: 1. Review of personnel records revealed that TP#2 was hired on November 23, 2020. 2. Review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209 signed by the Laboratory Director on 11/15/2022 indicated that TP #2 performed high complexity testing. 3. Review of laboratory policies revealed that the laboratory did not have a written policy /procedure for competency assessments. 4. Review of training and competency records for TP#2 revealed no documentation for annual competency for 2021.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, personnel credentials, personnel training records, and an interview with the lead testing person, the laboratory failed to ensure that all testing personnel met the minimum educational requirements for moderate complexity testing. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, personnel credentials, personnel records, patient record,

	and interview with laboratory staff, the laboratory failed to ensure that all qualification requirements to perform moderate complexity testing were met for 1 of 5 testing personnel. Findings included: 1. Review of the CMS Personnel Report Form 209 listed a total of 5 testing personnel (2 performing high complexity testing and 3 performing moderate complexity testing). 2. Review of the personnel credentials, revealed that the laboratory failed to have documentation of the highest level of education for TP#4, ensuring the qualification requirement to perform moderate complexity testing was met. 3. Personnel records provided revealed that testing person #4 was trained to perform moderate complexity testing from November 2021 to April 2022. TP#4 was trained in the following test system: Abbott Emerald (Cell Dyne) - instrument for performing Complete Blood Count (CBC) tests. 4. Random review of patient test records for 2022 revealed that TP#4 had resulted CBCs. A sampling of 9 patients resulted in 2022 by TP#4; Patient ID 90981, Date of test = 03/30/2022 Patient ID 100809, Date of test = 03/30/2022 Patient ID 71211, Date of test = 03/31/2022 Patient ID 86503, Date of test = 04/01/2022 Patient ID 63844, Date of test = 04/05 /2022 Patient ID 92076, Date of test = 04/06/2022 Patient ID 68904, Date of test = 04 /12/2022 Patient ID 82896, Date of test = 04/13/2022 Patient ID 79750, Date of test = 04/20/2022 5. During interview on 11/17/2022 at 9:30am, the lead testing person, after review of the records, confirmed the findings.