| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0055097 | 03/18/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bsa Physicians Group,Inc Dba Bsa Urgent Care Cente | 4510 S Bell St, Amarillo, TX | |

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 |
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| **D0000** | The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records and interview showed that the laboratory failed to self-grade results not scored by the PT agency in two of two events reviewed in 2023 and 2024. Findings follow. A. Review of the College of American Pathologists (CAP) Evaluation results for Clinical Microscopy (CM) PT records in the A 2023 and the B 2024 testing events showed the laboratory failed to self-grade results. The Evaluation for CM-A 2023 event, for sample USP-02 showed for Urine Sediment a Result of "See Note [27]". The Evaluation for CM-B 2024 event, for sample CMP-14 showed for Urine Sediment a Result of "See Note [27]". Review of the Participant Summary under "Actions Laboratories Should Take when a PT Result is Not Graded" stated for Code 27 Exception Reason Code Description: "Lack of participant or referee consensus." And, under Action Required stated, "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." Documentation of self-evaluation was requested on March 18, 2025 at 1100 hours but not provided. B. Interview with the Technical Consultant |

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| | (as listed on the CMS Form 209) on March 18, 2025, at 1100 hours in the office confirmed the findings. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) records, and interview, the laboratory failed to verify the accuracy of urine sediment microscopy, potassium hydroxide (KOH), and wet preps at least twice annually for one of four events reviewed in 2023 and 2024. Findings follow. A. Review of the College of American Pathologists (CAP) PT records from 2023 and 2024 showed one accuracy assessment in 2024 for urine sediment microscopy, KOH, and wet preps. Additional accuracy assessments were requested on March 18, 2025 at 1140 hours but not provided. B. Interview with the Technical Consultant (as listed on the CMS Form 209) on March 18, 2025 at 1140 hours confirmed they enrolled late in 2024 and missed an event. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's textbook procedure, the laboratory's policy and procedure, observation, test reports, pre-survey paperwork, and interview, the laboratory failed to follow itw own procedure for the volume, centrifugation speed and time for microscopic urinalysis for 2 out of 2 specimens tested on 03/18/2025. Findings follow. A. Review of the laboratory's textbook procedure from Urinalysis and Body Fluids1, Chapter on Urinalysis at Specimen Volume stated, "A standard amount of urine, usually between 10 and 15 mL, is centrifuged in a conical tube. This provides an adequate volume from which to obtain a representative sample of the |

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| | elements present in the specimen. A 12 mL volume is frequently used because multiparameter reagent strips are easily immersed in this volume, and capped centrifuge tubes are often calibrated to this volume. If obtaining a 12 mL specimen is not possible, as with pediatric patients, the volume of the specimen used should be noted on the test report." And under Centrifugation stated, "The speed of the centrifuge and the length of time the specimen is centrifuged should be consistent. Centrifugation for 5 minutes at a relative centrifugal force (RCF) of 400 produces an optimum amount of sediment with the least chance of damaging the elements. To correct for differences in the diameter of centrifuge heads, RCF rather than revolutions per minute (RPM) is used. The RPM value shown on the centrifuge tachometer can be converted to RCF using nomograms available in many laboratory manuals or by using the formula: RCF = 1.118 x 10 to the -5 x radius in centimeters x RPM squared Centrifugation calibration should be performed routinely. Use of the braking mechanism to slow the centrifuge causes disruption of the sediment before decantation and should be avoided. To prevent biohazardous aerosols, all specimens must be centrifuged in capped tubes." B. Review of the laboratory's policy and procedure titled, Urine Microscopic Examination, revised 02/2014, at Introduction stated, "In order for the results to be of value, a consistent method to obtain the urine sediment must be followed. An optimal 12 cc specimen is centrifuged at 1800 RPMs for 5 minutes..." C. During a tour of the laboratory on March 18, 2025 at 1135 hours it was observed on the Drucker Horizon 642 VES centrifuge the setting for urinalysis - setting 1 for 1800 RPM for 5 minutes as seen on the sticker attached to the centrifuge had been deleted from the centrifuge settings and the serum setting of 3200 RPM (1426 RCF) for 10 minutes was being used to spin urine for microscopic urinalysis. D. Review of the two patient's reports that had been reported that morning showed the following patients listed by Medical Record Number (MRN) tested for microscopic urinalysis: 1. 639690 2. 2000092305 E. Review of the pre-survey paperwork showed on the CMS Form 116 approximately 2350 microscopic urinalysis were performed annually. F. Interview with testing personnel #2 (as listed on the CMS Form 209) on March 18, 2023 at 1145 hours in the laboratory routinely spun 11 mL of urine and was manually breaking the centrifuge and was unaware that she was using the serum setting and its impact on urine sediment. She was unable to identify when the setting was no longer available on the centrifuge. Interview with the Technical Consultant on March 18, 2025 at 1445 hours in the laboratory confirmed the findings. 1. Strasinger, Susan King, and Marjorie Schaub Di Lorenzo. Urinalysis and Body Fluids, 6th Edition. F.A. Davis Company, 2014. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, quality control records, and interview, the laboratory failed to print the Beckman Coulter DxH 520 Complete Blood Count (CBC) quality control logs for 20 of 22 months reviewed. Findings follow. A. Review of the Beckman Coulter DxH 520 Instructions for Use, 03/2019, under Chapter 4 Quality Control at Quality Control Overview stated, "Quality Control is the routine monitoring of performance using commercial controls. Controls have known |

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| | characteristics when run on a given system and are analyzed periodically in the same manner that patient specimens are analyzed. The results of analyzed controls are then compared to the known characteristics using statistical methods. This comparison allows changes in the system performance to be detected. If the changes detected are significant, you can then take action to improve system, performance." At Printing Control Files on page 4-10 described how to print the control files. The control files show a summary of all QC runs for that lot, and identifies which controls were in or out of range, the statistical data like mean, standard deviation and coefficient of variation, the target values and limits, and the Levy-Jennings charts. B. Review of the quality control records showed no QC summary logs for 05/07/2023 - 02/09/2024 and 04/05/2024 - 03/11/2025. C. Interview with the Technical Consultant (as listed on the CMS Form 209) on March 18, 2025 at 1500 hours in the office confirmed the findings. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the test reports and interview, the laboratory failed to ensure the address was on the test reports for eight of eight reports reviewed from July 2024 - March 2025, nine months reviewed. Findings follow. A. Random review of eight test reports from July 2024 - March 2025 showed no facility name and address on the test reports as listed by date of service and Medical Record Number (MRN): Date MRN 1. 07/08/2024 492725 2. 11/24/2024 715663 3. 02/15/2025 2000177612 4. 02/27/2025 949222 5. 02/28/2025 520209 6. 02/28/2025 702590 7. 03/18/2025 639690 8. 03/18 /2025 2000092305 B. Interview with the Office Manager on March 18, 2025 at 1630 hours in the office stated they will stamp the reports with the facility name, but confirmed the reports do not have the address on them. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's textbook procedure, the laboratory's policy and procedure, observation, test reports, pre-survey paperwork, and interview, the laboratory director failed to ensure laboratory personnel could identify problems that may adversely affect test performance and test results. Findings follow. 1. Testing |

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| | personnel failed to identify the urine centrifugation speed and time setting had been deleted/removed from the centrifuge and was using serum settings to spin 2 out of 2 specimens tested on 03/18/2025 (see D5403). |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of personnel records, regulations, and interview, the laboratory director failed to specify in writing the duties and responsibilities of six of six testing personnel engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Finding follow. A. Review of the form Job Summary - Staff under "Skills & Abilities Preferred" did not include the duties and responsibilities of testing personnel #1-6 (as listed on the CMS Form 209). B. Review of the regulations for testing personnel responsibilities at 493.1425 (b) stated, "Each individual performing moderate complexity testing must- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results; (b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples; (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; (4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance; (5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and (6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications." C. Interview with the Office Manager on March 18, 2025 at 1005 hours confirmed they did not list CLIA duties and responsibilities for testing personnel. II. Based on review of personnel records and interview, the laboratory director failed to specify in writing the duties and responsibilities of one of one technical consultant. Finding follow. A. Review of personnel records showed no duties and responsibilities for the technical consultant. B. Interview with the Office Manager on March 18, 2025 at 1000 hours confirmed they did not have the duties and responsibilities for the technical consultant. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing records, competency evaluations, and |

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| | interview, the technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for four out of six testing personnel competencies reviewed for the Complete Blood Counts (CBC) on the Beckman Coulter DxH 520, microscopic urinalysis, potassium hydroxide (KOH), and wet preps in 2023 and 2024. Findings follow. A. Review of the College of American Pathologists (CAP) proficiency testing records attestation statements from the B and C events of 2023, and the B and C events of 2024 and A event of 2025 for the CBC for testing personnel #3, 4, 5, and 6 (as listed on the CMS form 209) did not participate in proficiency testing, and the A and B events of 2023 and B event in 2024 for microscopy showed testing personnel #3, 4, and 5 did not participate in proficiency testing. B. Review of the competency evaluations from 2023 and 2024 revealed the form was checked with a check mark indicating completion under the column for Assessment of Test Performance by Performing PT Samples for all testing personnel including testing personnel #3, 4, 5, and 6 for the CBC, and testing personnel #3, 4, and 5 for urine sediment, KOH and wet preps. C. Interview with the Technical Consultant (as listed on the CMS Form 209) on March 18, 2025 at 1045 hours confirmed test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing was not done for testing personnel #3, 4, 5, and 6. She said she thought PT meant performing patient samples [versus proficiency testing]. |
| **D6074** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(5)<br><br>(b)(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's textbook procedure, the laboratory's policy and procedure, observation, test reports, pre-survey paperwork, and interview, testing personnel failed to identify problems that may adversely affect test performance and test results. Findings follow. 1. Testing personnel failed to identify the urine centrifugation speed and time setting had been deleted/removed from the centrifuge and was using serum settings to spin 2 out of 2 specimens tested on 03/18/2025 (see D5403). |