Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0055097	05/14/2019
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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.801 Condition: enrollment and testing samples
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory failed to enroll in a proficiency testing program in a timely matter in order to participate in the first testing event of 2018 (three events per year) for the specialty of hematology. The findings included: 1. Review of the College of American pathologists (CAP) proficiency testing records from 2017 third testing event through 2019 first testing event found that the laboratory failed to participate in the first testing event of 2018 for hematology. 2. Interview of the technical consultant conducted on May 14, 2019 at 9:01 AM confirmed that the laboratory failed to enroll in a proficiency testing program in a timely matter in order to participate in the first testing event of 2018.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES

	CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records, instrument test records, review of policies and procedures and interview with facility personnel, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples. The findings included: 1. A review of the College of American Pathologists (CAP) proficiency testing records from 2017, 2018 and 2019 (three events per year) revealed five of five hematology proficiency samples from the first testing event of 2019 were each tested twice. 2. Review of the facility procedure titled External Proficiency Testing found under the heading Procedure: " The survey material will be analyzed as if it were a patient and, when possible, shall enter the patient workload as if it were a patient" 3. Interview of the Technical Consultant conducted on May 14, 2019 at 9:19 AM confirmed that the proficiency testing samples were tested twice, but testing personnel only tested patient specimens once.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing records for 2017 third testing event through 2019 first testing event and staff interview, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program for one of five testing events resulting in unsatisfactory performance for all analytes in the specialty of hematology. The findings include: 1. Review of the College of American Pathologists (CAP) proficiency testing records for 2018 third testing event through 2019 first testing event (three testing events per year) found that the laboratory failed to submit proficiency results for the 2018 third testing event to the proficiency testing agency for scoring prior to the cut off date. Failure to submit results to the proficiency testing agency resulted in a score of 0% for all analytes. 2. Interview of the technical consultant conducted on May 14, 2019 at 9:12 AM confirmed that proficiency testing results for the hematology 2018 third testing event were not submitted in a timely manner to be evaluated by the proficiency testing agency resulting in a score of 0% for all analytes.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or

	baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, centrifuge maintenance function checks, and confirmed in interview, the laboratory failed to define a function check protocol that ensures the accuracy of revolutions per minute (RPM) and the timer on the Drucker Diagnostics Model 642 centrifuge used to prepare urine specimens for urine sediment testing. The findings included: 1. Review of the Drucker Diagnostics Model 642 centrifuge operator's manual, under the heading of "Performance/Calibration", states: "Maximum speed depends on the incoming line voltage and the load being spun. a line voltage of 115 volts is required to achieve the speeds described in this manual. If the unit is running 10 percent slower than specified, it should be returned to your dealer or the Drucker Company for repair." 2. The laboratory's policy titled "Urinalysis - Microscopic Exam" under the section Procedure (Step-by-Step Instructions), states: " Spin for 5 minutes at 1800 rpm." 3. The laboratory's model 642 centrifuge was last checked by the biomedical department on December 3, 2018. The speed at the time of the inspection was noted as 3,210 RPM. 4. Interview of the biomed specialist conducted on May 15, 2019 at 11:12 AM confirmed that the laboratory did not have a policy to assess the centrifuge at the appropriate level for it preparing urine sediment. She. She continued that she only evaluated the centrifuge at the highest speed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Review of the laboratory's own Quality Assessment procedure, and interview of facility personnel found that the laboratory failed to follow it's own procedure for monthly quality assessment review. The findings included: 1. Review of the policy titled Quality Assurance found : "A Comprehensive quality assurance manual will be developed to contain all the quality assurance policies and procedures of the laboratory, evaluations of the effectiveness of these policies and procedures, and identification of corrective actions of identified problems." Further review found on page 2: "The laboratory director or technical consultant will discuss with the staff on at least a monthly basis the results of quality assurance review and ways the laboratory can improve on the quality of its work." 2. Interview of the Technical Consultant conducted on May 14, 2019 at 11:29 AM confirmed that the laboratory did not have a quality assurance manual and did not have documentation of monthly discussions with staff of quality assurance activities.
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: Review of proficiency testing records and interview of facility personnel found that the laboratory director failed to ensure that the laboratory was enrolled in an approved proficiency testing program for hematology in order to participate in the first testing event of 2018. (See D 2000)
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from 2017, 2018 and 2019 and staff interview, found the laboratory director failed to ensure proficiency test results were returned prior to the submission deadline in one of five events. (refer toD2123).