Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2108488	06/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Stat Laboratory	5115 El Paso Drive Suite B, El Paso, 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 of samples 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director
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: Based on a review of the laboratory testing records, CMS report 155, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for Bacteriology and Syphilis Serology in 2021. The findings included: 1. A review of facility records found no documentation of the laboratory being enrolled in or participating in a CMS approved proficiency testing program for Bacteriology or Syphilis Serology in 2021. The laboratory tested 54 patient specimens for Gram Stain and 741 patient specimens for Rapid Plasma Reagin (RPR) between January 1, 2021 and June 28, 2021. 2. Review of the CMS report 155 found no proficiency testing scores had been reported to the Centers for Medicare and Medicaid Services (CMS). 3. Interview of the Lead Medical Lab Scientist conducted on June 28, 2021 at 1:19 PM confirmed that the laboratory did not enroll in, or participate in a proficiency testing program for Bacteriology or Syphilis Serology in 2021.

D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Review of College of American Pathologist (CAP) proficiency testing records for 2019 and 2020 (three events per year), and interview of facility personnel found that the laboratory failed to retain records for two of six proficiency testing events for Gram Stain testing for at least two years. The findings included: 1. Review of the CAP proficiency testing records for Gram Stain found that the laboratory failed to retain records for each testing event as follows: a. D5A 2020 - The laboratory failed to retain instrument printouts, attestation statements and original submission forms. b. D5C 2020 - The laboratory failed to retain instrument printouts attestation statements and original submission forms. 2. Interview of the lead Medical Lab Scientist conducted June 28, 2021 at 2:32 PM confirmed that no other proficiency testing records were available for review.
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: Review of the CMS form 209 Laboratory Personnel Report, policies and procedures, personnel files and interview of facility personnel found that the laboratory failed to assess the competency of all testing personnel, supervisors and consultants performing Gram stain and RPR procedures in 2019, 2020 or 2021. THIS IS A REPEAT DEFICIENCY OF THE 10/28/2019 INSPECTION. The findings included: 1. Review of the CMS 209 Laboratory Personnel Report found the Laboratory Listed three Testing Personnel and one Technical Consultant performing Gram Stain and RPR procedures. 2. Review of policies and procedures found on page 2 of the policy titled Quality Management program under the heading procedure - "All new employees will receive formal orientation and training in all areas of responsibility and must demonstrate competency before being allowed to work independently. Competency is assessed within the first 6 months of hire and annually thereafter for all employees". 3 . Competency assessment records for all personnel were requested on June 28, 2021 at 1: 35 PM. Competency assessments were provided for two of three testing personnel performing RPR and Gram Stain test procedures. There were no competency assessment records available for review for testing person one to ensure his competency was assessed in 2019, 2020, or 2021. Testing person one was also designated as the technical consultant (effective March 2020). There was no competency assessment of the technical consultant available for review. 4. Interview of the lead Medical Lab Scientist conducted June 28, 2021 at 1:47 PM confirmed that competency assessments for testing person one and the technical consultant were not available for review.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview of facility personnel, the laboratory failed to have a quality assessment program to identify and correct problems in general Lab systems. The laboratory failed to enroll in a proficiency testing program for Gram Stain and Syphilis Serology in 2021. (See D 2000) The laboratory failed to ensure all proficiency testing records were kept for a minimum of two years. (see D 3037) The laboratory failed to have a procedure to assess all testing personnel, consultants and supervisors. (See D 5209)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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. This STANDARD is not met as evidenced by: Observations, review of policies and procedures, manufacturer instructions for use and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions as well as their own written instructions for performing RPR testing using the ASI RPR CARD TEST for SYPHILIS when testing patient specimens. The Findings follow: 1. Observations made in the laboratory June 28, 2021 at 3:26 PM found: a. The carbon antigen (used in RPR testing) stored in the test rack with the needle attached and the dropper bottle lid covering the needle. Testing personnel was not testing patient specimens at the time. b. Testing person three (listed on the CMS report 209 Laboratory Personnel report) was asked to demonstrate the daily procedure for ensuring the needle (used to dispense carbon antigen) met the manufacturer's requirements for use. a. Testing person three removed the carbon antigen dropper cap from the needle, then removing the needle from the antigen dropper bottle. b. Testing person three attached the needle to a 1 ml syringe and aspirated water to the 0.5 ml mark. c. Testing person three dispensed the water through the needle counting the drops. 32 drops were delivered by surveyor and testing person three counts. d. Testing person three stated he would then rinse the needle and reinstall it on the carbon antigen dropper bottle and place in the rack on the counter. 2. Review of the laboratory's own written policy found on page 3 under the heading Maintenance- " The needle assembly must washed in distilled or deionized water and air dried after each shift. Do not wipe the needle dry. Place the needle back into the plastic sleeve. Do not remove bottle tip when washing the needle assembly. Let the assembly air dry. Before next use, make sure that no large water droplets remain in the dropping bottle by shaking the bottle and squeezing it." Further review found on page 3 under the heading Calibration -"The needle should deliver 60 + 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the

	number of drops delivered in 0.5 mL. The needle is considered satisfactory if 30 + 1 drops are obtained in 0.5 mL." 3. Review of the manufacturer's instructions for use (revision 03/17) found on page 1 under section 6 HANDLING AND PROCEDURAL NOTES - "6.3 The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. Do not wipe the needle dry. Place the needle back into the plastic sleeve. Do not remove bottle tip when washing the needle assembly. Let the assembly air dry. Before next use, make sure that no large water droplets remain in the dropping bottle by shaking the bottle and squeezing it. 6.4 The needle should deliver 60 + 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 mL. The needle is considered satisfactory if 30 + 1 drops are obtained in 0.5 mL." Continued review found in section 7 STORAGE INSTRUCTIONS "7.1 Store all reagents at 2-8 degrees C (Celsius) in an upright position when not in use. Carbon Antigen may be stored for up to one month in the dropping bottle at 2-8 degrees C; in this case, the needle must be cleaned at the end of each shift using a syringe or pipet." 4. Interview of testing person three (hired 11/30/2020) on the CMS report 209 (Laboratory Personnel report) conducted June 28, 2021 at 3:38 PM confirmed that when he was trained to do the needle delivery check, he was trained using water and that he was unaware he needed to use the carbon antigen, stating he was trained by the technical consultant and testing person two. When asked about the storage of the carbon antigen he stated the "carbon antigen is kept at room temperature through the day and only stored in the refrigerator overnight."
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: Based on review of the laboratory policies and procedures and interview of facility personnel found the laboratory failed to have a written policy to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. The laboratory failed to ensure that RPR reagents were maintained at the appropriate temperature as specified in the manufacturers instructions for use. (See D5411)
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: Review of personnel files, laboratory records, quality control records and interview of facility personnel found the laboratory director failed to provide overall management

	and technical direction. Findings Included: 1. The laboratory director failed to ensure that testing personnel were performing test methods as required to ensure accurate and reliable results. (See D6014) 2. The laboratory director failed to ensure that they laboratory was enrolled in an HHS approved proficiency testing program for each specialty and subspecialty tested by the laboratory. (See D6015) 3. The laboratory director failed to ensure that the quality assessment programs had been established and maintained to assure the quality of laboratory testing. (See D6021) 4. The laboratory director failed to ensure that all testing personnel received the appropriate training prior to testing patient specimens. (See D6029) 5. The laboratory director failed to ensure that policies and procedures were established for monitoring the performance and competency of testing personnel. (See D6030)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Observations, review of the laboratory's own written policy, manufacturers instructions for use and interview of facility personnel found the laboratory director failed to ensure testing personnel were performing RPR procedures as required. (See D 5411)
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, patient test records and interview of facility personnel, the laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for gram stain and syphilis serology in 2021. (See D 2000)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation's, review of the policies and procedures, review of personnel records, proficiency testing records and staff interview, the laboratory director failed to ensure that the quality assessment program was established and maintained to assure the quality of testing. (See D5791)
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Observations, review of policies and procedures, and interview of testing personnel found the laboratory director failed to ensure that all testing personnel had been properly trained and demonstrated performance of RPR testing to ensure accurate and reliable results. (See D5411)
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: Review of policies and procedures, personnel records and interview of facility personnel found the laboratory director failed to ensure that all testing personnel, consultants and supervisors were assessed for competency in 2019 and 2020. (See D 5209)