Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0667597	03/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Brazos County Health District	201 North Texas Avenue, Bryan, 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
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 the laboratory's American Proficiency Testing (API) proficiency testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of 3 of 12 attestation statements being signed by those who were required to sign them. The findings were: 1. Review of API's attestation statement form 2019 (events 1, 2, and 3) for microbiology, Syphilis serology, and hematology/coagulation and 2020 (events 1, 2, 3) for microbiology, syphilis serology, and hematology/coagulation stated, "Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of API's attestation statement form 2019 (events 1, 2, and 3) for microbiology, Syphilis serology, and hematology/coagulation and 2020 (events 1, 2, 3) for microbiology, syphilis serology, and hematology/coagulation found the following attestation statements were not signed: 2020 (event 1) Hematology /Coagulation not signed by laboratory director (or designee) 2020 (event 1) Microbiology not signed by laboratory director (or designee) 3. An interview with testing personnel #1 (as listed on Form CMS-209) at 10:00 hours in the Health Authority office confirmed the findings Key: CMS - Centers for Medicare and Medicaid Services
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: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments for its Technical Supervisors, Technical Consultants and General Supervisor. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 03/25/2021) revealed the laboratory identified 2 Technical Supervisors, 2 Technical Consultants, and 1 General Supervisors. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of performing competency assessments on each supervisor and consultant identified. 3. An interview with technical consultant supervisor 1 (as listed on Form CMS 209) on 03/25/2021 at 1030 hours in the Health Authority office revealed the laboratory did not have documentation of assessing the competencies of the Technical Supervisors, Technical Consultants, and General Supervisor. This confirmed the 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 review of the laboratory's textbook procedure, the laboratory's policy and procedure, pre-survey docuements, observation, and interview, the laboratory failed to follow textbook procedure for performing Wet Preps used for the identification of trichomonas, clue cells, and yeast. Findings follow. 1. Review of the laboratory's textbook procedure from Clinical Methods: The History, Physical, and Laboratory Examinations, 3rd Edition, 1990, Chapter 179, Tests on Vaginal Discharge, under Technique stated, "To prepare a wet prep... Place the sample in 1ml of saline and agitate and mix. Take a drop of this mixture and place it on a slide..." 2. Review of the laboratory's policy and procedure titled, Sexually Transmitted Infections Microscopy Procedure, effective 03/11/2021, under Saline Wet Prep stated, "specimens are delivered to lab on cotton swabs preserved in 1-2 ml of normal saline within one hour of collection." 3. Surveyor observed on March 25, 2021 at 0920 hours in the TB Exam room, 3 Wet Prep vials filled with roughly 2 ml of saline. 4. Review of the pre-survey document Annual Test Volume & Proficiency Testing Programs Worksheet, showed an estimated 150 Wet Preps were performed annually. 5. Interview with technical consultant #1, on the CMS Form 209, on March 25, 2021 at 0915 hours in the laboratory acknowledged they used 1-2 mls of saline in the Wet Prep vials. KEY: ml = milliliter
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: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, pre-survey documents, and interview, the laboratory failed to perform the needle check each day of patient testing for the Rapid Plasma Reagin (RPR) procedure for Syphilis. Findings follow. 1. Review of the ASI RPR Card Test for Syphilis package insert under Handling and Procedural Notes stated, "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. This needle is considered satisfactory if 30 +/- 1 drops are obtained in 0.5 ml." 2. Review of the laboratory's policy and procedure Rapid Plasma Reagin (RPR) Procedure, effective 02 /03/2020, stated, "3. 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 ml syringe. Fill the syringe with 0.5 ml of the antigen suspension. While holding the syringe in a vertical position, count the number of drops delivered. This needle is considered satisfactory if 30 +/- 1 drops are obtained in 0.5 ml." Under Quality Control stated, "each new needle must be checked and obtain a 30 +/- drops per 0.5 ml of antigen." 3. Review of the pre-survey document Annual Test Volume & Proficiency Testing Programs Worksheet, showed an estimated 1050 RPRs were performed annually. 4. Interview with technical consultant #1, on the CMS Form 209, on March 25, 2021 at 0940 in the office acknowledged they do a needle check when they change needles using a new needle. When asked how do you know an old needle delivered the appropriate volume she responded "do not have an answer for that."
D5805	TEST REPORT CFR(s): 493.1291(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. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview, the laboratory failed to include the name of the laboratory on 15 out of 15 test reports for Gram Stains, Wet Preps, Rapid Plasma Reagin (RPR), and Treponema Pallidum Antibody. Findings follow. A. Test Reports 1. Review of 4 Gram Stain test reports showed the name of the laboratory was not on the report, as listed by patient ID and collection date: a. #7554, 8 /24/2020, b. #3262, 07/24/2020, c. #6161, 01/10/2020, d. #1741, 11/01/2019. 2. Review of 3 Wet Mount test reports showed the name of the laboratory was not on the

	report, as listed by patient ID and collection date: a. #1994, 01/04/2021, b. #12872, 11 /02/2020, c. #9559, 07/20/2020. 3. Review of 6 RPR (Rapid Plasma Reagin) test reports showed the name of the laboratory was not on the report, as listed by patient ID and collection date: a. #1980, 01/04/2021, b. #12872, 11/02/2020, c. #3262, 07/24 /2020, d. #9559, 07/20/2020, e. #189, 06/03/2020, f. #434, 01/09/2020. 4. Review of 2 Treponema Pallidum Antibody test reports showed the name of the laboratory was not on the report, as listed by patient ID and collection date: a. #189, 05/29/2020, b. #6735, 11/22/2019. B. Interview with technical consultant #1, on the CMS Form 209, on March 25, 2021 at 1135 hours in the office acknowledged she has tried to get that changed.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview, the laboratory failed to provide the reference ranges to the provider on 9 out of 15 test reports for Gram Stains, Wet Preps, and Treponema Pallidum Antibody. Findings follow. 1. Review of 4 Gram Stain test reports showed no reference ranges on the patient test report, as listed by patient ID and collection date: a. #7554, 8/24/2020, b. #3262, 07/24/2020, c. #6161, 01 /10/2020, d. #1741, 11/01/2019. 2. Review of 3 Wet Mount test reports showed no reference ranges on the patient test report, as listed by patient ID and collection date: a. #1994, 01/04/2021, b. #12872, 11/02/2020, c. #9559, 07/20/2020. 3. Review of 2 Treponema Pallidum Antibody test reports showed no reference ranges on the patient test report, as listed by patient ID and collection date: a. #189, 05/29/2020, b. #6735, 11/22/2019. 4. Interview with technical consultant #1, on the CMS Form 209, on March 25, 2021 at 1140 hours in the office confirmed the test reports had no reference ranges for the Gram Stain, Wet Prep, and Treponema Pallidum Antibody.