Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0863781	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
City Of Port Arthur Health Dept Lab	5860 9th Ave, Port Arthur, 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	During an onsite laboratory recertification inspection, the laboratory was found out of compliance with the CLIA regulations. The following condition not met was: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems;
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 review of laboratory proficiency testing (PT) records and confirmed in interview, the laboratory failed to ensure proficiency testing samples were tested in the same manner as patient samples for two of two hematology/coagulation PT events in 2023. The findings included: 1. Review of the 2023 Hematology / Coagulation PT event attestation statements had the following statement: "The undersign certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." 2. Review of the 2023 Hematology / Coagulation PT event attestations had the following testing personnel (TP) performing the test for Vaginal Wet Preparation. 2023 Event 1: 3/29/2023 TP1 and TP2 2023 Event 3: 11/8 /2023 TP1 and TP2 Surveyor asked if both testing persons review patients before resulting; the laboratory director (LD) stated that only one TP review and result Vaginal Wet Preparation. 3. In an interview on 3/13/2024 at 09:39 hours, in the laboratory, the LD confirmed that the 2023 PT for Vaginal Wet Preparation was not performed in the same manner as patients.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including

	instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory documents and confirmed in interview, the laboratory failed to retain the instructions for use (IFU) for three of four kit tests performed, the Arlington Scientific RPR Card Test for Syphilis, the Syphilis Health Check for Rapid Syphilis, and the BioLytical Laboratory HIV-1/HIV-2 Antibody Test kits, for records reviewed in 2023. The findings included: 1. Review of laboratory testing included the Arlington Scientific RPR Card Test for Syphilis testing. Surveyor asked for the manufacturer's IFU and none was provided. 2. In a tour of the facilities on 3/13/2024 at 09:50 hours, the surveyor noted the following kit test available for use by staff: BioLytical INST HIV-1 / HIV-2 Antibody Test On 3/13/2024 at 10:00 hours, the Assistant Health Director stated that nurses perform the following two kit tests, as needed, on patients: Health Check for Rapid Syphilis BioLytical INST HIV-1 / HIV-2 Antibody Test The surveyor asked for the manufacturer's IFU, and none was provided. 3. In an interview on 3/13/2024 at 10:10 hours, in the laboratory, the laboratory director stated the IFU for the RPR Card Test for Syphilis was not available for personnel, and that they did not actively keep track of the testing being performed by the nurses and were unaware they needed to retain the records.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based upon review of the policies and procedures, manufacturer instructions, patient test records, observations and interview of faciity personnel, the laboratory failed to meet the analytic system requirements for non waived testing in Bacteriology and Syphilis Serology. NOTE: This is a repeat deficiency from the October 2021 survey. Based on record review and confirmed in interview the laboratory failed to have a step by step policy for the receiving, testing, reporting, and review of proficiency testing samples. (See D 5401) Review of the laboratory policy titled "Wet Mount" did not include instructions for the specimen collection, labeling, storage, transportation, and criteria for specimen acceptability and rejection. (See D 5403) The laboratory failed to follow the manufacturer's instructions when performing the RPR procedure. (see D 5411)
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 record review and confirmed in interview, the laboratory failed to have a step by step policy for the receiving, testing, reporting, and review of proficiency testing samples for records reviewed in 2022 and 2023. NOTE: This is a repeat deficienciey from the October 2021 survey. The findings included: 1. Review of the laboratory policies did not include a step-by-step procedure for the receiving, testing, reporting, and review of proficiency testing (PT) samples. On 3/13/2024 at 10:10 hours Surveyor asked the laboratory director (LD) for the PT policy, and none was provided. 2. In an interview on 3/13/2024 at 10:15 hours, in the laboratory, the laboratory director confirmed that the laboratory did not have a step by step policy for the receipt, testing, reporting, and review of PT samples.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, annual test volumes, and confirmed in interview, the laboratory failed to have a policy to include the requirements for specimen collection, labeling, storage, transportation, and criteria for specimen acceptability and rejection, for records reviewed for 2023. NOTE: This is a repeat deficienciey from the October 2021 survey. The findings included: 1. Review of the laboratory policy titled "Wet Mount" did not include instructions for the specimen collection, labeling, storage, transportation, and criteria for specimen acceptability and rejection. On 3/13/2024 at 10:00, Testing personnel (TP) 2 stated that the specimens were collected elsewhere in the building and walked over to the laboratory for testing. Surveyor asked for laboratory provided instructions to personnel collecting the vaginal wet mount for testing and none was provided. 2. Review of the Centers for Medicare and Medicaid (CMS) form 116, section VIII "Non-Waived" testing listed an estimated annual test volume of 1,045 for the specialty of Microbiology. 3. In an interview on 3/13/2024 at 10:20 hours, in the laboratory, the laboratory director

	confirmed that the laboratory's policy for vaginal wet prep procedures did not include information for the collection, labeling, storage, transportation, and criteria for specimen acceptability and rejection.
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 upon observations, review of policies and procedures, manufacturer's instructions and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the reagin antigen, failed to follow the assay protocol for testing and failed to store the reagent as directed by the manufacturer when testing 158 patient samples for RPR (Rapid Plasma Reagin) between September 1, 2023 and December 31, 2023. The findings included: 1. Based upon observations made upon entry in the laboratory at 09:15 AM, the RPR antigen and controls were located on the counter next to the refrigerator. During demonstration of the RPR antigen needle check by testing person 2 conducted March 13, 2024 at 10:46 AM, he used water to verify the volume dispensed by the needle and repeatedly used a Kim Wipe tissue to wipe the needle as he pushed air through the barrel of the syringe. Continued observations found testing person 2 dispensed samples to the well, followed by the reagent. He proceeded to spread the specimen and reagent across the test circle using the flat end of the dispenstir, followed by "tapping" the flat end of the dispenstir 2 to 3 times in the specimen (at 10:47 AM) before disposal. 2. The laboratory had no written procedure with step by step instructions for performing RPR testing. 3. Review of the manufacturer's instructions (printed from the Internet during the inspection) found under the heading HANDLING AND PROCEDURAL NOTES: "1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples. 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 under Step 3 :"Do not wipe the needle dry." Continued review found under the heading Storage instructions:" Store all reagents at 2-8 C in an upright position when not in use." Further review found on page 3 under the heading ASSAY PROTOCOL: "Using a stirrer pipet, dispense one free falling drop (0.05ml) of each serum or plasma sample onto a separate circle on the test card. Using the flat end of the stirrer pipet, spread the sample over the entire area of the test circle. Do not scratch the surface of the test area. Attach the needle to the dropping bottle. Dispense one free-falling drop of the antigen suspension onto each sample while holding the dropper bottle in a vertical suspension. Do not restir the sample and antigen." 3. Review of daily RPR logs for September through December 2023 found the laboratory tested 158 patient specimens for RPR. 4. During interview of testing person 2 conducted March 13, 2024 at 10:47 AM, he confirmed that the laboratory did not have a written procedure to provide step by step instruction for performing the RPR

	test, and did not have a copy of the manufacturer's instructions. When asked what he used as his procedure, he stated "All I have is my 20 years of experience." He went on to say that when he arrived in the morning , he would remove the reagents and controls from the refrigerator and leave them at room temperature for the day.
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 upon review of the policies and procedures, manufacturer instructions, patient test records, observations and interview of faciity personnel, the laboratory failed to have a quality assurance program to monitor, assess and correct problems for non waived testing in Bacteriology and Syphilis Serology. The findings included: Based on record review and confirmed in interview, the laboratory failed to have a step by step policy for the receiving, testing, reporting, and review of proficiency testing samples. (See D 5401) Review of the laboratory policy titled "Wet Mount" did not include instructions for the specimen collection, labeling, storage, transportation, and criteria for specimen acceptability and rejection. (See D 5403) The laboratory failed to follow the manufacturer's instructions when performing the RPR procedure. (see D 5411)
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: Based upon observations, review of policies and procedures, manufacturer's instructions and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the reagin antigen, failed to follow the assay protocol for testing and failed to store the reagent as directed by the manufacturer when testing 158 patient samples for RPR (Rapid Plasma Reagin) between September 1, 2023 and December 31, 2023. (See D 5411) NOTE: This is a repeat deficiency from the October 2021 survey.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing (PT) records and confirmed in interview, the laboratory failed to ensure proficiency testing samples were tested in the same manner as patient samples for two of two hematology/coagulation PT events in 2023. (See D 2010)
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based upon review of policies and procedures, proficiency testing records, and interview of facility personnel found the laboratory director failed to ensure an approved procedure manual was available to testing personnel for performing non waived testing in Bacteriology and Syphilis Serology. (See D5401 and D5403) NOTE: This is a repeat deficiency from the October 2021 survey.