Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0863781	10/06/2021
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	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. 1230 Condition: General Lab Systems 493. 1250 Condition: Analytic Systems 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director 493. 1409 Condition: Laboratories Perfoming Moderate Complexity Testing; Technical Consultant 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel
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 the laboratories proficiency testing records, observations, review of patient test records and interview of facility personnel found the laboratory failed to enroll and participate in a proficiency testing program for Treponema pallidum antibodies using the Syphilis Health Check. The Findings included: 1. Review of the American Proficiency Institute Proficiency testing records for 2020 and 2021 (three events per year) found no documentation that the laboratory participated in a proficiency testing program for Treponema pallidum antibodies. 2. Observations made in the laboratory found the laboratory used the diagnostics direct Syphilis Health Check for detection of Treponemal antibodies in serum. 3. Review of patient test records found the

	laboratory tested 101 patient specimens in 2020 and 21 in 2021. 4. Interview of the laboratory director conducted October 6, 2021 at 10:22 AM confirmed the laboratory did not participate in a proficiency testing program for Treponema pallidum antibodies.
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: Review of proficiency testing records for 2020 and 2021 and interview of facility personnel found that the laboratory director and testing personnel failed to attest to the routine integration of proficiency samples into the patient workload in one of three testing events for Microbiology, and one of three testing events for Immunology in 2020. Findings were as follows: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2020 and 2021(three events per year) found the laboratory director and testing personnel had not signed the attestation statements for the 2020 3rd testing event for Immunology and the 2020 3rd testing event for Microbiology. 2. Interview of the Laboratory Director conducted October 6, 2021 conducted at 10:09 AM confirmed that attestation statements had not been signed. He stated he "doesn't usually use that page, he usually prints it out."
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 the laboratory's proficiency testing records and interview of facility personnel found the laboratory failed to retain proficiency testing records and attestation statements for one of five Microbiology proficiency events in 2020 and 2021, for at least two years. The findings included: 1. Review of the 2020 and 2021 American Proficiency Institute proficiency testing records (three events per year) found the laboratory failed to retain the original proficiency testing documents and the attestation statement for the 2021 Microbiology 2nd event. 2. Interview of the Laboratory Director conducted October 6, 2021 at 10:28 AM confirmed that the original documents and the attestation statement were not available for review.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Observations,review of policies and procedures, review of the laboratory proficiency testing records and interview of facility personnel found that the laboratory failed to meet the general lab systems requirements for testing in Microbiology and Syphilis Serology. The laboratory failed to ensure that the laboratory director and testing personnel attested to the routine integration of proficiency specimens into the normal patient workload for two of 10 events reviewed. (see D 2009) The laboratory failed to ensure that all proficiency testing records were retained for at least two years. (see D 3037) The laboratory failed to ensure that the proficiency testing results were evaluated and review of the results was documented by the appropriate personnel. (see D 5211)
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Review of the laboratory's proficiency testing records and interview of facility personnel found the laboratory failed to document the review of proficiency testing results for one of five Microbiology proficiency events in 2020 and 2021. The findings included: 1. Review of the 2020 and 2021 American Proficiency Institute proficiency testing records (three events per year) found the laboratory failed to document the review for the 2021 Microbiology 2nd event. 2. Interview of the Laboratory Director conducted October 6, 2021 at 10:28 AM confirmed that he had not documented his review of the proficiency results.
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: Observations,review of policies and procedures, review of the laboratory proficiency testing records and interview of facility personnel found that the laboratory failed to have a quality assessment program failed to monitor, assess and correct problems found in maintaining the proficiency testing records. The laboratory failed to ensure that the laboratory director and testing personnel attested to the routine integration of proficiency specimens into the normal patient workload for two of 10 events reviewed. (see D 2009) The laboratory failed to ensure that all proficiency testing records were retained for at least two years. (see D 3037) The laboratory failed to ensure that the proficiency testing results were evaluated and review of the results was documented by the appropriate personnel. (see D 5211) Interview of the laboratory Director conducted October 6, 2021 at 11:10 AM confirmed that the laboratory did not have a written quality assessment procedure. He stated that he "did have one at one time."

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 on review of manufacturer's instructions, policies and procedures, personnel records, observations and interview of facility personnel the laboratory failed to meet the analytic system requirements for non waived testing in Bacteriology and Syphilis Serology. Observations, review of policies and procedures and interview of facility personnel found the laboratory failed to have a written procedure for the preparation of Gram Decolorizer used for performing Gram stain procedures on patient specimens. (See D 5403) The laboratory failed to ensure expired reagents were not used in staining of patient specimens for the Gram Stain using the EDM3 Gram Stain Set. (see D 5417) The laboratory failed to test at least a positive and negative quality control material each day of patient testing when testing patient serum specimens for the Treponema pallidum antibodies using the Diagnostics Direct Syphilis Health Check. (See D5447)
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: Observations, review of policies and procedures and interview of facility personnel found the laboratory failed to have a written procedure for the preparation of Gram Decolorizer used for performing Gram stain procedures on patient specimens. The findings included: 1. Observations made during the tour of the laboratory found the laboratory was using the EDM3 Gram Stain Set for staining patient specimens. The

	Gram Stain decolorizer bottle (lot 0073 Expiration 2022-03-13 R 6-21-21) was near full, 2. Review of policies and procedures found no procedure available to testing personnel for the preparation of Gram Decolorizer. 3. Interview of the laboratory Director conducted on October 6, 2021 at 9:54 AM learned the laboratory was preparing their own Gram Decolorizer using equal parts of Everclear and Acetone, and using the previous bottle for storage. He confirmed that he did not relabel the container with the preparation date or its contents. Interview of testing person 2 conducted at 11:37 AM confirmed her made the new decolorizer on Monday and did not relabel the bottle used to store the decolorizer. He went on to say he has "made it twice and it lasts about a month".
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Review of manufacturers instructions for use, observations, review of patient logs and interview of facility personnel found the laboratory failed to ensure that expired reagents were not used in Gram Stain of patient specimens. The findings included: 1. Review of manufacturer's instructions for the Healthlink EDM3 Gram Stain Set Stabilized and Traditional Iodine found under the heading GRAM IODINE PREPARATION - "When following the traditional protocol, add the Gram Iodine concentrate to the Gram Iodine Diluent and mix well. Discard the solution three months from mixing." 2. Observations made in the laboratory found the Gram Iodine reagent bottle labeled "op 6-17-21" (opened 06/17/2021). 3. Review of patient logs found the laboratory had used the expired Gram Iodine in the staining of 14 patient specimens since the expiration on 09/17/2021 as follows: Two patient specimens were tested using the expired Gram Iodine on September 20, 2021 One patient specimen was tested using the expired Gram Iodine on September 21, 2021 One patient specimen was tested using the Gram Expired Gram Iodine on September 24, 2021 Three patient specimens were tested using the expired Gram Iodine on September 28, 2021 One patient specimen was tested using the expired Gram Iodine on September 29, 2021 Four patient specimens were tested using the expired Gram Iodine on October 1, 2021 Two patient specimens were tested using the expired Gram Iodine on October 4, 2021 4. Interview of the Laboratory Director confirmed that the expired Gram Iodine was used for staining patient specimens. He stated he had" borrowed some from a local hospital that he can use".
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Observations, review of patient test records and interview of facility personnel found the laboratory failed to test a negative and positive control each day of patient testing in 2020 and 2021 for Treponema pallidum antibodies using the Syphilis Health Check . The Findings included: 1. Observations made in the laboratory found the laboratory was currently using the Diagnostics Direct Syphilis Health Check lot 13100 Expiration 2022 -10-30 (R 12-4-20) for detection of Treponemal antibodies in serum. 2. Review of patient test records found the laboratory tested 101 patient specimens in 2020 and 21 in 2021 without documenting quality control procedures each day of patient testing. 4. Interview of Testing person one on the CMS report 209 Laboratory Personnel Report conducted October 6, 2021 at 10:52 AM confirmed that the laboratory did not test a negative and positive control each day of patient testing when using the Diagnostics Direct Syphilis Health Check . She stated that she " documented the quality control on the box each time she opened a new box." When asked if she kept the boxes, she stated she did not. When asked what date she performed quality control testing on lot 13100 Expiration 2022 -10-30 (R 12-4-20) (currently in use with no documentation of QC on the box), she stated she "did not know".
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: Observations,review of policies and procedures, review of the laboratory proficiency testing records and interview of facility personnel found that the laboratory failed to have a quality assessment program failed to monitor, assess and correct problems found in non waived testing. Observations, review of policies and procedures and interview of facility personnel found the laboratory failed to have a written procedure for the preparation of Gram Decolorizer used for performing Gram stain procedures on patient specimens. (See D 5403) The laboratory failed to ensure expired reagents were not used in staining of patient specimens for the Gram Stain. (see D 5417) The laboratory failed to test at least a positive and negative quality control material each day of patient testing when testing patient serum specimens for the Treponema pallidum antibodies using the Diagnostics Direct Health Check. (See D5447) Interview of the laboratory Director conducted October 6, 2021 at 11:10 AM confirmed that the laboratory did not have a written quality assessment procedure. He stated that he "did have one at one time."
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: Observations, review of policies and procedures, proficiency testing records, manufacturer's instructions, quality control records, personnel records and interview

	of facility personnel, The laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure the laboratory was enrolled in a proficiency testing program for Treponema pallidum antibody testing. (see D 6015) The laboratory director failed to ensure that proficiency testing records were tested as required and all proficiency testing records were retained for a minimum of two years. (See D6016) The laboratory director failed to ensure that all proficiency testing results had been reviewed to evaluate the laboratory's performance. (See D 6018) The laboratory director failed to ensure the laboratory had established and maintained a quality control program for Treponemal antibody testing. (See D 6020) The laboratory director failed to establish and maintain a quality assessment program to identify and correct failures in quality. (See D 6021) The laboratory director failed to ensure that all testing personnel received training for all procedures prior to testing patient specimens. (See D 6029) The laboratory director failed to ensure an approved procedure was available to testing personnel for the preparation and use of reagents and solutions. (See D 6031)
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 Treponema pallidum antibody testing in 2019, 2020 and 2021. (See D 2000)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel the laboratory director failed to ensure that attestation statements were signed by testing personnel and the laboratory director and the laboratory retained all proficiency testing records for a minimum of two years. (See D 2009 and D 3137)
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: Review of proficiency testing results and interview of facility personnel found the laboratory failed to ensure proficiency testing results were reviewed to evaluate the laboratory's performance. (see D 5211)
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Review of quality control records, patient test records and interview of facility personnel found the laboratory director failed to establish and maintain a quality control program for Treponema pallidum antibody testing. (See D 5447)
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: Observations, review of policies and procedures, manufacturers instructions, quality control records, patient test records, and interview of facility personnel found the laboratory director failed to establish and maintain a quality assessment program to assure the quality of laboratory services. (See D 5291 and D 5791)
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: Review of personnel files and interview of facility personnel found the laboratory director failed to ensure that all testing personnel had received the appropriate training prior to testing patient specimens. (See D 6066)
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: Review of policies and procedures and interview of facility personnel found the laboratory director failed to ensure the laboratory had a written procedure available to testing personnel for the preparation of Gram Decolorizer. (see D 5403)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Review of the CMS report 209, personnel records and interview of facility personnel found the Technical Consultant failed to provide technical oversight of the laboratory. The Technical Consultant failed to assess the competency of all testing personnel performing Syphilis Serology testing ,Gram Stain and wet mount procedures at least annually in 2019, 2020 and 2021.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Review of personnel records and interview of facility personnel found the technical

	consultant failed to ensure that competency assessments were completed on all testing personnel at least annually after their first year of testing patient specimens. One of two testing personnel had no annual competency assessments performed in 2019, 2020 or 2021. Findings included: 1. Review of personnel files found that Testing Personnel listed on the CMS Report 209 Laboratory Personnel Report (date of hire 2010) . Review of competency assessment records found the last competency assessment available for review was completed 06/12/2018. There were no other competency assessments available for review. 2. Interview of the laboratory director conducted October 6, 2021 at 09:15 AM confirmed that competency assessments had not been performed since the 2018 assessment.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report, personnel records and staff interview, it was revealed that one of two testing personnel failed to have documentation of training required to perform non waived testing for Syphilis Serology, Bacteriology and Parasitology procedures.(see D6066).
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Review of the CMS report 209 personnel report, personnel records and interview of facility personnel found the laboratory failed to document the training of one of two testing personnel performing non waived testing procedures in Bacteriology and Syphilis Serology. The Findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory identified two individuals as testing personnel. 2. Review of personnel files found no documentation of training for testing person two (hired July 26,2021). 3. Interview of the laboratory director conducted October 6, 2021 at 9:22 AM confirmed he did not document training of testing person two.