Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0863781	02/07/2022
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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Review of proficiency testing records, patient test records and interview of facility personnel found the laboratory failed to achieve an overall score of at least 80 percent in one of three Microbiology testing events for Gram Stain in 2021. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2021 found the laboratory achieved a score of 40 percent in the 2021 3rd testing event. The laboratory submitted unacceptable responses for specimens GS-12, GS-13 and GS-15. 2. Review of patient test records found the laboratory tested 31 patient specimens for Gram Stain procedures in October 2021. 3. Interview of the Laboratory Director conducted February 7, 2022 at 11:00 AM confirmed that the laboratory did not achieve a passing score of 80 percent in the API Microbiology 3rd event for Gram Stains. He went on to say that he had determined the cause of the failure was use of his homemade decolorizer. He replaced the homemade decolorizer with a commercially available decolorizer on November 1, 2021. When asked if patient specimens were assessed to determine if they might have been affected by the use of the homemade decolorizer, he stated he "did not (assess patient results) because the controls worked".
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2)

	Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Review of proficiency testing records, patient test records and interview of facility personnel found the laboratory failed to undertake appropriate training and document remedial actions when the laboratory received an unacceptable score of at least 80 percent in one of three Microbiology testing events for Gram Stain in 2021. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2021 found the laboratory achieved a score of 40 percent in the 2021 3rd testing event. The laboratory submitted unacceptable responses for specimens GS-12, GS-13 and GS-15. 2. Review of patient test records found the laboratory tested 31 patient specimens for Gram Stain procedures in October 2021. 3. Interview of the Laboratory Director conducted February 7, 2022 at 11:00 AM confirmed that the laboratory did not achieve a passing score of 80 percent in the API Microbiology 3rd event for Gram Stains. He went on to say that he had determined the cause of the failure was use of his homemade decolorizer. He replaced the homemade decolorizer with a commercially available decolorizer on November 1, 2021. When asked if patient specimens were assessed to determine if they might have been affected by the use of the homemade decolorizer, he stated he "did not (assess patient results) because the controls worked". No remedial actions and no additional training of testing personnel performing the failing event were taken.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Review of the submitted Centers for Medicare and Medicaid Services (CMS) 116 form, proficiency testing records, proficiency testing order confirmation for 2022 and interview of facility personnel found the laboratory failed to verify the accuracy of results for Potassium Hydroxide (KOH) wet mounts at least twice annually in 2020 or 2021. The findings included: 1. Review of the CMS-116 form submitted on the initial day of survey (October 6, 2021) found the laboratory reported performing an annual volume of 374 KOH wet prep tests. 2. Review of laboratory records for 2020 and 2021 found the laboratory failed to perform twice annual accuracy assessment for Wet Prep testing or be enrolled in a proficiency testing program. 3. Review of the 2022 enrollment form for participation in the American Proficiency Institute (API) proficiency testing program found the laboratory did not enroll for the KOH wet prep testing events. 4. Interview of the laboratory director conducted February 7, 2022 at 11:00 AM confirmed he did not enroll in the 2022 proficiency testing program for the KOH wet mount testing or have another means of assessing the accuracy of results at least twice annually.