Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660728	10/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
City Of Lubbock Health Dept Laboratory	2015 50th Street, Lubbock, 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
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: Based on observation, review of patient logs, and interview, the laboratory failed to ensure reagents were not used beyond their expiration date for wet preps and KOH (Potassium Hydroxide) preps on 8 patients reviewed from 9/21/2020 - 10/08/2020. Findings follow. Observation of an open box of Remel saline tubes in the refrigerator showed 13 available tubes with an expiration date of 9/11/2020. These tubes were used to collect the wet prep/KOH preps. Review of the patient log from 9/21/2020- 10 /08/2020 showed 8 wet preps and KOH preps were performed on the following patients: PH1809610 collected and tested on 9/21/2020, LB050408 collected and tested on 9/22/2020, LB047953 collected and tested on 9/23/2020, LB031342 collected and tested on 9/29/2020, LB050574 collected and tested on 10/01/2020, LB052371 collected and tested on 10/05/2020, LB048584 collected and tested on 10/5 /2020, and PH1838194 collected and tested on 10/06/2020. Interview with the technical consultant on 10/08/2020 at 1420 hours in the laboratory verified the wet prep/KOH saline tubes were expired. Interview with the technical consultant on 10/08 /2020 at 1500 hours in the breakroom acknowledged the nurses maintained those supplies.
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: Based on review of the laboratory's College of American Pathologist's (CAP) proficiency testing records from 2019 and 2020 and interview of facility personnel, the laboratory director failed to ensure the laboratory was enrolling in proficiency testing for the absence and or presence of gram negative diplococci. The findings included: 1. A review of the laboratory's CAP proficiency testing records from 2019 and 2020 found the laboratory participated in a proficiency testing program for Gram Staining consisting of five challenges each, three times each year for Gram Stain and Morphology. a. Proficiency testing event D5-A 2019 Gram Stain did not include the identification of Gram negative diplococci b. Proficiency testing event D5-B 2019 Gram Stain included one specimen challenging the identification of Gram negative diplococci c. Proficiency testing event D5-C 2019 Gram Stain included one specimen challenging the identification of Gram negative diplococci d. Proficiency testing event D5-A 2020 Gram Stain included one specimen challenging the identification of Gram negative diplococci e. Proficiency testing event D5-A 2020 Gram Stain did not include the identification of Gram negative diplococci 2. The laboratory was asked to provide documentation of being enrolled as required. No documentation was provided. 3. An interview with the technical consultant conducted on October 8, 2020 at 10:15 AM confirmed the laboratory was not enrolled in proficiency program specific for the absence or presence of gram negative diplococci. She also confirmed that they were not enrolled in a proficiency testing program for dark field microscopy to demonstrate Treponema pallidum. She thought participation in the proficiency testing program for gram stain would cover that.