

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0660728	<b>(X3) Date Survey Completed</b> 01/18/2022
<b>Name of Provider or Supplier</b> City Of Lubbock Health Dept Laboratory	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, rotator speed checks, patient testing records and interview, the laboratory failed to perform rotator speed checks at least once per day of patient testing for the ASI (Arlington Scientific Inc) RPR card test for Syphilis for 25 out of 34 days of patient testing from 11/02/2021 - 12/29/2021. Findings follow. A. Review of the ASI RPR Card Test for Syphilis package insert (6004-900 11-2016), under Assay Procedure for Qualitative at step 5 stated, "Place the card on an automatic rotator and cover to maintain humidity. Rotate at 100 +/- 5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds). Following rotation, a brief hand rotation and tilting of the card (at least 3-4 times) should be performed to aid in differentiating nonreactive from minimally reactive results." And the Assay Procedure for Semiquantitative for titers at step 8 stated, "Place the card onto the automatic rotator and cover to maintain humidity. Rotate at 100 +/- 5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds). Following rotation, a brief hand rotation and tilting of the card (3-4 times) should be performed to aid in differentiating nonreactive from minimally reactive results." B. Review of the laboratory's policy and procedure titled "Rapid Plasma Reagin 18mm Circle card (RPRC) ASI Card Test for Syphilis," revised 04/14/2016, under 13. Test Procedure at 13.1 Pre-Test Quality Control at 13.1.2 Verify Rotator Speed stated, "13.1.2.1. Rotator speed must be 100 +/- 5 rpm 13.1.2.2. Check the number of rotations per minute by lightly holding a pencil against the rotator platform. Using a digital timer, count the number of rotations in a 1 minute period. 13.1.2.3. Record results on the QC checklist. 13.1.2.4. QC Frequency:</p>

Weekly." C. Review of the rotator speed checks from 11/02/2021 - 12/29/2021 showed the rotator speed check was performed once per week: 1. 11/01/2021 2. 11/08/2021 3. 11/15/2021 4. 11/22/2021 5. 11/29/2021 6. 12/06/2021 7. 12/13/2021 8. 12/20/2021 9. 12/28/2021 D. Review of patient testing records showed rotator speed checks not performed on the following 25 days of patient testing: 1. 11/02/2021: 11 patients 2. 11/04/2021: 12 patients 3. 11/05/2021: 1 patient 4. 11/09/2021: 2 patients 5. 11/10/2021: 7 patients 6. 11/11/2021: 4 patients 7. 11/12/2021: 8 patients 8. 11/16/2021: 18 patients 9. 11/17/2021: 8 patients 10. 11/18/2021: 6 patients 11. 11/19/2021: 6 patients 12. 11/24/2021: 4 patients 13. 11/30/2021: 13 patients 14. 12/01/2021: 3 patients 15. 12/02/2021: 51 patients 16. 12/03/2021: 4 patients 17. 12/07/2021: 6 patients 18. 12/08/2021: 7 patients 19. 12/09/2021: 11 patients 20. 12/14/2021: 14 patients 21. 12/15/2021: 8 patients 22. 12/16/2021: 11 patients 23. 12/21/2021: 2 patients 24. 12/22/2021: 2 patients 25. 12/23/2021: 6 patients E. Interview with the Technical Consultant #2, listed on the CMS Form 209, on January 18, 2022 at 1130 in the breakroom acknowledged they performed the rotator speed checks weekly. Interview with the Technical Consultant #1, listed on the CMS Form 209, on January 18, 2022 at 1400 confirmed she had spoken to technical support and the rotator speed check was to be performed at least once each day of patient testing.