

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2189668	<b>(X3) Date Survey Completed</b>  05/19/2023
<b>Name of Provider or Supplier</b>  Lillie's Lab Solutions	<b>Street Address, City, State</b>  3901 East Stan Schlueter Loop Suite 103, Killeen, 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>D3027</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1)</p> <p>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on an unannounced revisit of the laboratory 05/04/2023 - 04/19/2023, review of the test requisition slip, patient instrument print-outs, and interview, the laboratory failed to retain a test requisition slip for two of two months reviewed for 130 of 130 patients tested from Jan 1, 2023 - Jan 23, 2023, and April 3, 2023 - May 3, 2023. Findings follow. A. Test requisitions were requested on May 4, 2023 at 1320 but not provided. B. Random review of patient instrument print-outs from testing performed from Jan 1, 2023 - Jan 31, 2023 and April 3, 2023 - May 3, 2023 showed the following patients listed by date of testing and patient ID: Date of Testing Patient ID 1. 01/10/23 2301100002 2. 01/10/23 2301100001 3. 01/10/23 000439005 4. 01/11/23 00043890022 5. 01/11/23 0004390017 6. 01/11/23 0004390020 7. 01/11/23 0004389798 8. 01/11/23 2301100001 9. 01/11/23 0004390017 10. 01/11/23 0004389732 11. 01/12/23 0004390034 12. 01/12/23 0004390036 13. 01/13/23 0004390089 14. 01/13/23 0004390041 15. 01/13/23 0004390043 16. 01/13/23 2301120001 17. 01/16/23 0004389902 18. 01/16/23 0004389744 19. 01/16/23 004389770 20. 01/16/23 0004389671 21. 01/17/23 0004389732 22. 01/17/23 0004390034 23. 01/17/23 004389770 24. 01/17/23 0004390130 25. 01/17/23 0004390169 26. 01/17/23 0004390043 27. 01/17/23 0004390134 28. 04/03/23 R0000764633 29. 04/03/23 R0000764629 30. 04/03/23 R0000764647 31. 04/03/23 R0000764646 32. 04/04/23 R0000764629 33. 04/04/23 R0000764635 34. 04/04/23 R0000764650 35. 04/04/23 R0000764649 36. 04/04/23 0004391207 37. 04/04/23 R0000764648 38. 04/05/23 R0000764651 39. 04/05/23 R0000764629 40. 04/06/23</p>

R0000764652 41. 04/06/23 R0000764629 42. 04/06/23 R0000764640 43. 04/06/23 R0000764639 44. 04/06/23 R0000764641 45. 04/06/23 23012370001 C. Interview with testing personnel, as listed on the CMS form 209 dated 05/04/2023, on May 4, 2023 at 1320 hours confirmed there were no patient requisitions for the testing performed. Interview with the owner on May 4, 2023 at 1325 hours acknowledged they draw the sample, but leave the requisition slips with the provider, and put the patient's name, date of birth, and tests ordered on the tube. She confirmed there was no requisition slip with who ordered the test along with the patient's information [to include name, sex and age, or date of birth, the tests to be performed, and the date and time of collection]. Interview with the owner on May 18, 2023 at 1040 hours acknowledged the phlebotomist was keeping requisitions for a week and then shredding them, and still trying to figure that 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:

Based on an unannounced revisit of the laboratory 05/04/2023 - 05/19/2023, review of proficiency testing (PT) records, email, and interview, the laboratory failed to retain all PT records for Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN (Blood Urea Nitrogen), Total Bilirubin, Calcium, Protein, Albumin, ALP, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, HDL (High-Density Lipoprotein), Triglycerides, Uric Acid, and Magnesium performed on the Alfa-Wasserman for 2 out of 3 days of testing reviewed. A. Phone interview with the Laboratory Director on February 6, 2023 at 1440 acknowledged the laboratory had testing issues on 01/27/2023 and had performed Proficiency testing on 01/27/2023 and repeated again on 01/29/2023. B. Review of the Proficiency testing records from the 1st event of 2023 from API (American Proficiency Institute) showed testing was performed on 1/31/2023. Additional records of PT tested from 01/26/2023 - 01/30/2023 were requested on May 4, 2023 at 1255 but not provided. C. Interview with testing personnel, as listed on the CMS form 209 dated 05/04/2023, on May 4, 2023 at 1305 confirmed Proficiency testing was only performed on 1/31/2023, and all the records of testing were in the binder. D. Email from the former Laboratory Director on May 16, 2023 at 5:08 PM showed instrument print-outs of the Proficiency testing performed on 1/29/2023 for samples CH-01 - CH-05. E. Further interview on May 19, 2023 at 1405 hours with testing personnel acknowledged he didn't remember sending any reports to the Laboratory Director, only screen shots. Further interview on May 19, 2023 at 1424 hours with testing personnel confirmed Proficiency testing was performed on 01/29/2023 after owner viewed instrument print-outs obtained from former laboratory director.