

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1077790	<b>(X3) Date Survey Completed</b>  11/15/2022
<b>Name of Provider or Supplier</b>  Kenneth A Giraldo Md Pa	<b>Street Address, City, State</b>  1219 Se Ave Ste 101, Sarasota, FL	
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>D5785</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: 'Based on observation, record review, and interview with the Laboratory Director, the laboratory failed to document corrective action for unacceptable freezer temperatures for 57 out of 132 days (July 6, 2022 - November 15th, 2022) where 47 patient specimens (#1-#47) were being stored prior to performing testing. Findings included: Observation on 11/15/22 at 9:25 a.m. revealed 47 patient urine specimens, awaiting testing for urine pH, cannabinoids, and opiates, were found in the laboratory's frost free freezer. Review of the Manufacturer's Instructions (MI) for the opiate reagent kit stated "If the sample cannot be analyzed immediately, it may be stored refrigerated (2 degrees to 8 degrees Celsius) for up to 3 days. For longer storage, up to 12 months, keep sample frozen (-20 degrees Celsius) and then thaw before use." Review of the MI for the cannabinoid reagent kit stated "If the sample cannot be analyzed immediately, it may be stored refrigerated at 2 - 8 degrees Celsius for up to 3 days. For longer storage keep sample frozen at -20 degrees Celsius and then thaw before use. Studies have shown that [cannabinoid] analytes in urine are stable at -20 degrees and then thaw before use." Record review of the laboratory's "Preventative Maintenance Procedure" stated "Freezers should maintain a temperature of &gt; -18 degrees Celsius." This temperature range is 2 degrees warmer than the MI. Record review of the laboratory's temperature log indicated a freezer temperature range of &gt; -20 degrees Celsius. Record review of the laboratory's temperature log revealed the following temperatures were outside of MI and no corrective action was taken: 1. 07/06/2022: -14.9 degrees Celsius 2. 07/11/2022: -17.5 degrees Celsius 3. 07/13/2022: -17.6 degrees Celsius 4. 07/14/2022: -16.3 degrees Celsius 5. 07/15/2022: -14.2</p>

degrees Celsius 6. 07/18/2022: -15.2 degrees Celsius 7. 07/19/2022: -16.2 degrees Celsius 8. 07/20/2022: -16.7 degrees Celsius 9. 08/01/2022: -15.1 degrees Celsius 10. 08/02/2022: -15.3 degrees Celsius 11. 08/04/2022: -14.7 degrees Celsius 12. 08/05/2022: -14.5 degrees Celsius 13. 08/08/2022: -14.7 degrees Celsius 14. 08/09/2022: -17.5 degrees Celsius 15. 08/10/2022: -18.1 degrees Celsius 16. 08/11/2022: -17.5 degrees Celsius 17. 08/12/2022: -14.7 degrees Celsius 18. 08/15/2022: -15.0 degrees Celsius 19. 08/16/2022: -14.0 degrees Celsius 20. 08/17/2022: -15.7 degrees Celsius 21. 08/18/2022: -18.5 degrees Celsius 22. 08/19/2022: -18.0 degrees Celsius 23. 08/22/2022: -15.7 degrees Celsius 24. 08/23/2022: -17.0 degrees Celsius 25. 08/24/2022: -17.1 degrees Celsius 26. 08/25/2022: -17.2 degrees Celsius 27. 08/29/2022: -15.6 degrees Celsius 28. 08/30/2022: -17.1 degrees Celsius 29. 08/31/2022: -17.7 degrees Celsius 30. 09/01/2022: -16.3 degrees Celsius 31. 09/02/2022: -18.0 degrees Celsius 32. 09/06/2022: -15.1 degrees Celsius 33. 09/07/2022: -14.5 degrees Celsius 34. 09/08/2022: -16.2 degrees Celsius 35. 09/09/2022: -15.2 degrees Celsius 36. 09/12/2022: -17.4 degrees Celsius 37. 09/13/2022: -15.2 degrees Celsius 38. 09/14/2022: -17.4 degrees Celsius 39. 09/15/2022: -17.0 degrees Celsius 40. 09/16/2022: -17.9 degrees Celsius 41. 09/19/2022: -16.2 degrees Celsius 42. 09/20/2022: -15.9 degrees Celsius 43. 10/04/2022: -15.7 degrees Celsius 44. 10/05/2022: -17.4 degrees Celsius 45. 10/06/2022: -15.0 degrees Celsius 46. 10/10/2022: -15.6 degrees Celsius 47. 10/11/2022: -16.5 degrees Celsius 48. 10/13/2022: -17.3 degrees Celsius 49. 10/20/2022: -14.6 degrees Celsius 50. 10/21/2022: -14.8 degrees Celsius 51. 10/27/2022: -15.7 degrees Celsius 52. 10/28/2022: -15.5 degrees Celsius 53. 10/31/2022: -15.7 degrees Celsius 54. 11/01/2022: -17.6 degrees Celsius 55. 11/07/2022: -14.9 degrees Celsius 56. 11/08/2022: -15.9 degrees Celsius 57. 11/11/2022: -17.3 degrees Celsius

During a telephone interview on 11/15/22 at 12:15 p.m., the Laboratory Director stated he was unaware the acceptable range on the laboratory temperature logs was incorrect and was unaware the freezer temperatures were out of range where the urine specimens were being stored for future testing. He stated that he and the General Supervisor had reviewed the correct temperature for urine specimen storage.