

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2097512	(X3) Date Survey Completed 12/23/2020
Name of Provider or Supplier Reliance Pathology Partners Llc-Mobile	Street Address, City, State 5747 Hoover Blvd, Tampa, FL	
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
D0000	An announced CLIA recertification survey was conducted at Reliance Pathology Partners LLC Mobile on 12/23/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when the room temperature for the mobile van was out of range for 50 days out of 236 days (January 2019 - December 2020) reviewed. Findings included: Record review of the "Cryostat and Van Temperature Quality Assurance" and the "Frozen Checklist" forms revealed that the room temperature range was 75 degrees +/- 5 degree Fahrenheit (F). Continued review of these forms revealed temperatures were out of range with no corrective action documented for the following dates: 1. January 3, 2019: documented temperature of "87F" 2. January 10, 2019: documented temperature of "68.9F" 3. January 15, 2019: documented temperature of "67F" 4. January 17, 2019: documented temperature of "64.2F" 5. January 21, 2019: documented temperature of "57.4F" 6. February 7, 2019:</p>

documented temperature of "64F" 7. February 14, 2019: documented temperature of "66.3F" 8. February 21, 2019: documented temperature of "62.7F" 9. February 28, 2019: documented temperature of "59.1F" 10. March 5, 2019: documented temperature of "65.6F" 11. March 6, 2019: documented temperature of "50F" 12. March 7, 2019: documented temperature of "68F" 13. March 21, 2019: documented temperature of "69.1F" 14. March 29, 2019: documented temperature of "63F" 15. April 4, 2019: documented temperature of "68F" 16. April 23, 2019: documented temperature of "80.5F" 17. May 2, 2019: documented temperature of "69.7F" 18. June 11, 2019: documented temperature of "82F" 19. June 25, 2019: documented temperature of "81F" 20. June 27, 2019: documented temperature of "82F" 21. August 1, 2019: documented temperature of "67.5F" 22. August 20, 2019: documented temperature of "88F" 23. September 30, 2019: documented temperature of "81.7F" 24. October 1, 2019: documented temperature of "84.8F" 25. October 17, 2019: documented temperature of "81.2F" 26. October 18, 2019: documented temperature of "83.7F" 27. October 21, 2019: documented temperature of "83.7F" 28. October 22, 2019: documented temperature of "80.2F" 29. November 13, 2019: documented temperature of "63.6F" 30. November 14, 2019: documented temperature of "68F" 31. November 20, 2019: documented temperature of "62F" 32. November 25, 2019: documented temperature of "58.4F" 33. December 5, 2019: documented temperature of "62F" 34. December 19, 2019: documented temperature of "59.1F" 35. December 20, 2019: documented temperature of "69.7" 36. December 21, 2019: documented temperature of "68F" 37. January 6, 2020: documented temperature of "67F" 38. January 9, 2020: documented temperature of "67.7F" 39. January 22, 2020: documented temperature of "65.1F" 40. January 23, 2020: documented temperature of "62F" 41. February 3, 2020: documented temperature of "58F" 42. February 7, 2020: documented temperature of "67.5F" 43. February 10, 2020: documented temperature of "65.5F" 44. February 20, 2020: documented temperature of "69F" 45. February 21, 2020: documented temperature of "65.4F" 46. February 28, 2020: documented temperature of "61.7F" 47. March 2, 2020: documented temperature of "68.2F" 48. March 9, 2020: documented temperature of "63.1F" 49. December 4, 2020: documented temperature of "65F" 50. December 18, 2020 : documented temperature of "69F" On 12/23/20 at 11:30 AM, the Laboratory Manager confirmed the temperatures were out of range. The Laboratory Manager stated the non-regulated testing personnel didn't know to take action when room temperature was out of range.