

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0876532	(X3) Date Survey Completed 09/20/2021
Name of Provider or Supplier Presidential Womens Center Lp	Street Address, City, State 100 Northpoint Pkwy, West Palm Beach, 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 recertification survey was conducted on 9/20/21 at Presidential Womens Center LP, a clinical laboratory in West Palm Beach, Florida. Presidential Womens Center LP is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the standard level deficiency:
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant, the laboratory failed to follow manufacturer's instructions for room temperature requirement for where RH (immunoematology test) and hCG (pregnancy test) testing was performed in the laboratory. Room Temperatures were out of range for 136 out of 557 days. The findings included: Record review of package inserts for "Blood Grouping Reagent Anti - D Blend" and "Henry Schein OneStep+ - hCG Combo test" revealed that the "Blood Grouping Reagent Anti - D Blend" stated, It is recommended to allow reagents to reach 20 - 24 degrees Celsius (68 - 75 degrees Fahrenheit) before testing and the "Henry Schein OneStep+ - hCG Combo test" revealed the statement "Allow the test cassette, urine or serum specimens and/or controls to equilibrate to room temperature (15 - 30 degree Celsius/59 - 86 degrees Fahrenheit) prior to testing." Record review of the "Ambient Temperatures Log for the Laboratory" logs showed</p>

the acceptable temperature range was 32 - 122 Fahrenheit. The following temperatures were documented: 1. 07/25/2019: "67.3" 2. 07/29/2019: "67.3" 3. 08/05/2019: "66.4" 4. 08/07/2019: "67.8" 5. 08/10/2019: "66.9" 6. 08/20/2019: "67.8" 7. 08/26/2019: "67.8" 8. 09/09/2019: "67.6" 9. 09/16/2019: "67.1" 10. 09/17/2019: "67.1" 11. 10/21/2019: "67.5" 12. 11/09/2019: "67.6" 13. 11/14/2019: "67.1" 14. 03/12/2020: "67.8" 15. 03/14/2020: "67.6" 16. 03/18/2020: "60.8" 17. 03/19/2020: "67.8" 18. 03/23/2020: "67.3" 19. 03/25/2020: "60.8" 20. 03/26/2020: "67.6" 21. 04/01/2020: "67.1" 22. 04/11/2020: "67.1" 23. 04/13/2020: "67.1" 24. 04/15/2020: "67.8" 25. 04/16/2020: "67.3" 26. 04/18/2020: "67.8" 27. 04/20/2020: "67.8" 28. 04/21/2020: "67.1" 29. 04/25/2020: "67.3" 30. 04/28/2020: "67.3" 31. 04/29/2020: "67.6" 32. 04/30/2020: "67.8" 33. 05/02/2020: "66.2" 34. 05/04/2020: "67.8" 35. 05/05/2020: "67.3" 36. 05/06/2020: "66.7" 37. 05/07/2020: "66.4" 38. 05/09/2020: "66.0" 39. 05/12/2020: "66.7" 40. 05/15/2020: "66.4" 41. 05/23/2020: "66.7" 42. 05/28/2020: "67.6" 43. 05/30/2020: "67.8" 44. 06/01/2020: "66.9" 45. 06/08/2020: "67.8" 46. 06/10/2020: "67.1" 47. 06/11/2020: "67.8" 48. 06/13/2020: "67.0" 49. 06/15/2020: "66.0" 50. 06/16/2020: "66.9" 51. 06/18/2020: "67.8" 52. 06/20/2020: "67.8" 53. 06/23/2020: "67.8" 54. 06/29/2020: "66.9" 55. 07/01/2020: "67.8" 56. 07/02/2020: "67.1" 57. 07/09/2020: "67.8" 58. 07/13/2020: "66.9" 59. 07/14/2020: "67.6" 60. 07/15/2020: "66.4" 61. 07/16/2020: "67.8" 62. 07/20/2020: "66.7" 63. 07/22/2020: "67.8" 64. 07/27/2020: "66.2" 65. 07/28/2020: "67.8" 66. 07/30/2020: "67.1" 67. 08/01/2020: "67.3" 68. 08/03/2020: "66.4" 69. 08/04/2020: "67.8" 70. 08/05/2020: "67.8" 71. 08/06/2020: "67.3" 72. 08/08/2020: "67.8" 73. 08/10/2020: "67.3" 74. 08/11/2020: "66.9" 75. 08/13/2020: "67.1" 76. 08/17/2020: "66.4" 77. 08/18/2020: "67.1" 78. 08/19/2020: "67.6" 79. 08/22/2020: "66.4" 80. 08/24/2020: "67.8" 81. 08/25/2020: "66.9" 82. 08/29/2020: "67.7" 83. 08/31/2020: "67.8" 84. 09/01/2020: "67.3" 85. 09/03/2020: "67.3" 86. 09/08/2020: "67.6" 87. 09/09/2020: "67.1" 88. 09/10/2020: "66.9" 89. 09/14/2020: "66.7" 90. 09/15/2020: "66.2" 91. 09/17/2020: "67.1" 92. 09/21/2020: "67.8" 93. 09/22/2020: "67.3" 94. 09/23/2020: "66.9" 95. 09/24/2020: "67.1" 96. 09/28/2020: "67.3" 97. 10/01/2020: "67.8" 98. 10/05/2020: "67.3" 99. 10/12/2020: "67.8" 100. 10/15/2020: "67.8" 101. 10/17/2020: "67.6" 102. 10/20/2020: "67.8" 103. 11/03/2020: "67.3" 104. 11/07/2020: "67.2" 105. 11/11/2020: "67.1" 106. 11/14/2020: "67.8" 107. 11/16/2020: "66.7" 108. 11/17/2020: "67.6" 109. 11/19/2020: "67.8" 110. 11/21/2020: "66.7" 111. 11/23/2020: "67.8" 112. 11/24/2020: "67.3" 113. 11/25/2020: "67.8" 114. 11/28/2020: "67.6" 115. 11/30/2020: "67.3" 116. 12/05/2020: "67.1" 117. 12/30/2020: "67.1" 118. 01/20/2021: "67.8" 119. 01/27/2021: "67.1" 120. 02/09/2021: "67.3" 121. 02/17/2021: "67.7" 122. 02/24/2021: "67.1" 123. 03/03/2021: "67.1" 124. 03/11/2021: "67.1" 125. 03/13/2021: "67.8" 126. 03/29/2021: "66.7" 127. 03/30/2021: "67.3" 128. 04/03/2021: "67.8" 129. 04/08/2021: "66.9" 130. 04/10/2021: "67.1" 131. 04/15/2021: "67.3" 132. 05/04/2021: "67.6" 133. 05/17/2021: "67.7" 134. 05/20/2021: "67.4" 135. 06/01/2021: "67.9" 136. 09/11/2021: "67.8"

Interview on 09/20/21 at 2:00 p.m., the Technical Consultant confirmed that the temperature range was not in accordance with the manufacturer's temperature range for "Blood Grouping Reagent Anti - D Blend" and the "Henry Schein OneStep+ - hCG Combo test" test cassette, urine, or serum specimens and/or controls but for the intrauterine device (IUD) storage. She stated she did not know there was room temperature ranges for the Anti - D and the pregnancy tests.