

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0719719	(X3) Date Survey Completed 02/07/2022
Name of Provider or Supplier St Petersburg Womans Health Center	Street Address, City, State 3401 66 St N, Saint Petersburg, 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 St Petersburg Woman's Health Center on 02/07/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 observation, record review, and interview with the Director of Personnel, the laboratory failed to perform patient testing at the required temperature for 155 days out of 185 days (10/25/2019 - 02/04/2022) that temperatures were recorded. Findings Included: Observation on 02/07/2022 at 09:55 am, revealed an Insignia RVB - BL Rh view box. This device is a blood typing tool used in Rh determination. Record review of the manufacturer's instructions for the Blood Grouping Reagent Anti-D (Monoclonal Blend) Gamma Clone revealed "Place 1 drop of Gamma-clone Anti-D (Monoclonal Blend) on a warm (approximately 45 degrees Celsius) slide on a lighted view box." Record review of the laboratory's procedure titled "RH Control" revised on 11/27/2005 revealed the Rh view box temperature was to be 40-50 degree Celsius (C). Record review of the "Daily Laboratory Log Sheet" revealed the following Rh view box out of range temperatures that were documented: 1. 01/15/20: 35 degrees C 2. 01/17/20: 35 degrees C 3. 01/22/20: 35 degrees C 4. 01/24/20: 35</p>

degrees C 5. 01/29/20: 35 degrees C 6. 01/31/20: 35 degrees C 7. 02/05/20: 35
degrees C 8. 02/07/20: 35 degrees C 9. 02/12/20: 35 degrees C 10. 02/14/20: 35
degrees C 11. 02/19/20: 35 degrees C 12. 02/21/20: 35 degrees C 13. 02/26/20: 35
degrees C 14. 02/28/20: 35 degrees C 15. 03/04/20: 35 degrees C 16. 05/22/20: 35
degrees C 17. 05/27/20: 35 degrees C 18. 05/29/20: 35 degrees C 19. 06/03/20: 35
degrees C 20. 06/05/20: 35 degrees C 21. 06/10/20: 35 degrees C 22. 06/12/20: 35
degrees C 23. 06/17/20: 35 degrees C 24. 06/19/20: 35 degrees C 25. 06/24/20: 35
degrees C 26. 06/26/20: 35 degrees C 27. 07/01/20: 35 degrees C 28. 07/03/20: 35
degrees C 29. 07/08/20: 35 degrees C 30. 07/10/20: 35 degrees C 31. 07/15/20: 35
degrees C 32. 07/17/20: 35 degrees C 33. 07/22/20: 35 degrees C 34. 07/24/20: 35
degrees C 35. 07/29/20: 39 degrees C 36. 07/31/20: 35 degrees C 37. 08/05/20: 35
degrees C 38. 08/07/20: 35 degrees C 39. 09/16/20: 35 degrees C 40. 09/18/20: 35
degrees C 41. 09/23/20: 35 degrees C 42. 09/25/20: 35 degrees C 43. 10/01/20: 35
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degrees C 74. 01/29/21: 35 degrees C 75. 02/05/21: 35 degrees C 76. 02/10/21: 35
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degrees C 143. 11/10/21: 37 degrees C 144. 12/29/21: 35 degrees C 145. 12/31/21: 38
degrees C 146. 01/05/22: 37 degrees C 147. 01/07/22: 38 degrees C 148. 01/12/22: 35
degrees C 149. 01/14/22: 37 degrees C 150. 01/19/22: 37 degrees C 151. 01/21/22: 37
degrees C 152. 01/26/22: 37 degrees C 153. 01/28/22: 38 degrees C 154. 02/02/22: 38
degrees C 155. 02/04/22: 37 degrees C On 02/07/22 at 12:00 pm, the Director of
Personnel stated when the laboratory got the new Rh view box, the Insignia Rh View
Box User's & Service Manual stated "Rh slides reaches temperature of 37 degrees (+/-

2 degrees) in 5 to 10 minutes, eliminating wasteful heat up time." The Director of Personnel reported that he was told by the Laboratory Director to follow the temperature range for the view box and not the reagent.