

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0290593	(X3) Date Survey Completed 04/01/2022
Name of Provider or Supplier Tampa Womens Health Center Inc	Street Address, City, State 2010 E Fletcher Ave, 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 Tampa Woman's Health Center on 03/29/2022 - 04/01/2022. 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 interview with the co-director, the laboratory failed to document corrective action when the refrigerator temperature was out of range for 13 out of 622 days from January 22, 2020 to March 28, 2020 and when the room temperature was out of range for 525 out of 625 days. Findings included: Record review of the manufacturer's instructions for the "Immucor Blood Grouping Reagent Anti-D (Monoclonal Blend) Gamma-clone by Slide, Tube, or Microwell Test" revealed "Store at 1 to 10 degrees Celsius [equal to 33.8-50 degrees Fahrenheit] when not in use." Review of the "Daily Laboratory Log Sheet" revealed the following unacceptable refrigerator temperatures were documented: 2022 January 4: 54 degrees Fahrenheit January 10: 56 degrees Fahrenheit February 8: 28 degrees Fahrenheit February 9: 56 degrees Fahrenheit February 12, 14, 15: 54 degrees Fahrenheit March</p>

1: 52 degrees Fahrenheit March 2: 54 degrees Fahrenheit March 10: 51 degrees Fahrenheit March 16, 17: 51 degrees Fahrenheit March 24: 52 degrees Fahrenheit Record review of the "Insignia Rh View box" User & Service Manual" revealed "Operating Ambient Temperature: 27 +/- 4 degrees Celsius" [73 - 87 degrees Fahrenheit]. Continued review of the logs revealed the following unacceptable room temperatures were documented: 2020 January 22, 23: 69 degrees Fahrenheit January 24: 71 degrees Fahrenheit January 25: 72 degrees Fahrenheit January 27: 71 degrees Fahrenheit January 29: 70 degrees Fahrenheit January 30, 31: 69 degrees Fahrenheit February 1: 71 degrees Fahrenheit February 3: 69 degrees Fahrenheit February 5: 71 degrees Fahrenheit February 8, 10: 70 degrees Fahrenheit February 22: 70 degrees Fahrenheit February 24: 72 degrees Fahrenheit February 28, 29: 70 degrees Fahrenheit March 2: 70 degrees Fahrenheit March 5, 9: 72 degrees Fahrenheit March 13: 70 degrees Fahrenheit March 20: 71 degrees Fahrenheit March 24: 70 degrees Fahrenheit March 26: 67.3 degrees Fahrenheit March 27: 69 degrees Fahrenheit March 31: 70 degrees Fahrenheit April 2, 3, 11: 70 degrees Fahrenheit April 15-18, 22-25, 29-30: 72 degrees Fahrenheit May 1-2, 6-9, 13: 72 degrees Fahrenheit May 14-15: 71 degrees Fahrenheit May 16, 20-29: 72 degrees Fahrenheit June 1: 71 degrees Fahrenheit June 2: 72 degrees Fahrenheit June 3: 68 degrees Fahrenheit June 4: 72 degrees Fahrenheit June 6: 69 degrees Fahrenheit June 9-10: 68 degrees Fahrenheit June 11: 72 degrees Fahrenheit June 12-13: 69 degrees Fahrenheit June 16: 72 degrees Fahrenheit June 17: 69 degrees Fahrenheit June 18: 70 degrees Fahrenheit June 19: 72 degrees Fahrenheit June 20: 71 degrees Fahrenheit June 22-23: 72 degrees Fahrenheit June 24: 68 degrees Fahrenheit June 25: 72 degrees Fahrenheit June 26-27: 71 degrees Fahrenheit June 29-30: 68 degrees Fahrenheit July 2: 71 degrees Fahrenheit July 3: 70 degrees Fahrenheit July 6: 72 degrees Fahrenheit July 7: 71 degrees Fahrenheit July 8: 69 degrees Fahrenheit July 9: 72 degrees Fahrenheit July 10: 70 degrees Fahrenheit July 11: 69 degrees Fahrenheit July 13: 72 degrees Fahrenheit July 14: 70 degrees Fahrenheit July 15: 67 degrees Fahrenheit July 16-18: 70 degrees Fahrenheit July 20: 71, 72 degrees Fahrenheit July 21: 67 degrees Fahrenheit July 22: 68 degrees Fahrenheit July 23: 72 degrees Fahrenheit July 24, 27: 71 degrees Fahrenheit July 28: 70 degrees Fahrenheit July 29: 71 degrees Fahrenheit July 30-31: 70 degrees Fahrenheit August 1: 70 degrees Fahrenheit August 3: 66 degrees Fahrenheit August 4: 70 degrees Fahrenheit August 5: 68 degrees Fahrenheit August 6: 71 degrees Fahrenheit August 7: 69 degrees Fahrenheit August 8: 71 degrees Fahrenheit August 10: 67 degrees Fahrenheit August 12: 68 degrees Fahrenheit August 13: 67 degrees Fahrenheit August 14-15, 17: 70 degrees Fahrenheit August 18-19: 69 degrees Fahrenheit August 20: 67 degrees Fahrenheit August 21: 71 degrees Fahrenheit August 22: 69.9 degrees Fahrenheit August 24: 72.4 degrees Fahrenheit August 25: 69 degrees Fahrenheit August 26: 69.6 degrees Fahrenheit August 27-28: 71 degrees Fahrenheit August 29: 68.8 degrees Fahrenheit August 31: 70.8 degrees Fahrenheit September 1: 69 degrees Fahrenheit September 2: 69.1 degrees Fahrenheit September 3: 69 degrees Fahrenheit September 5, 8: 68 degrees Fahrenheit September 9: 67 degrees Fahrenheit September 10: 68 degrees Fahrenheit September 11: 71 degrees Fahrenheit September 12, 15: 68 degrees Fahrenheit September 16: 67 degrees Fahrenheit September 17-18: 71 degrees Fahrenheit September 19: 68 degrees Fahrenheit September 21: 72 degrees Fahrenheit September 23: 70 degrees Fahrenheit September 24: 69 degrees Fahrenheit September 25: 70 degrees Fahrenheit September 26: 71 degrees Fahrenheit October 2: 72 degrees Fahrenheit October 5: 71.9 degrees Fahrenheit October 6: 69.5 degrees Fahrenheit October 7-8: 69 degrees Fahrenheit October 9: 70 degrees Fahrenheit October 10: 69.2 degrees Fahrenheit October 12: 71.3 degrees Fahrenheit October 13: 69 degrees Fahrenheit October 14: 70.2 degrees Fahrenheit October 15: 72 degrees Fahrenheit October 16: 69 degrees Fahrenheit October 17: 68 degrees Fahrenheit October 19: 69 degrees Fahrenheit October 20: 71

degrees Fahrenheit October 21: 69 degrees Fahrenheit October 22: 69.6 degrees Fahrenheit October 23: 69 degrees Fahrenheit October 24: 70 degrees Fahrenheit October 28: 71.3 degrees Fahrenheit October 29: 72 degrees Fahrenheit October 30: 69 degrees Fahrenheit November 2-4: 70 degrees Fahrenheit November 5: 72 degrees Fahrenheit November 6: 71.8 degrees Fahrenheit November 7: 69.2 degrees Fahrenheit November 9: 71.7, 71 degrees Fahrenheit November 10: 69 degrees Fahrenheit November 11, 13, 16: 70 degrees Fahrenheit November 19: 72 degrees Fahrenheit November 20: 69.5 degrees Fahrenheit November 21, 23: 70 degrees Fahrenheit November 24: 72 degrees Fahrenheit November 25: 71 degrees Fahrenheit November 27-28: 70 degrees Fahrenheit December 2: 70 degrees Fahrenheit December 3: 69.5 degrees Fahrenheit December 4-5: 71 degrees Fahrenheit December 7: 72 degrees Fahrenheit December 8: 70 degrees Fahrenheit December 9: 69 degrees Fahrenheit December 10-11: 70 degrees Fahrenheit December 12: 72 degrees Fahrenheit December 14: 69 degrees Fahrenheit December 15-16: 71.8 degrees Fahrenheit December 17: 72 degrees Fahrenheit December 18: 68 degrees Fahrenheit December 19: 69.5 degrees Fahrenheit December 21: 71 degrees Fahrenheit December 22: 71.6 degrees Fahrenheit December 23: 70 degrees Fahrenheit December 24: 72 degrees Fahrenheit December 26: 68 degrees Fahrenheit December 28: 67 degrees Fahrenheit December 29: 69 degrees Fahrenheit December 30: 71 degrees Fahrenheit December 31: 72 degrees Fahrenheit 2021 January 2, 4-5: 70 degrees Fahrenheit January 6-7, 9: 71 degrees Fahrenheit January 11: 68 degrees Fahrenheit January 12: 71 degrees Fahrenheit January 13: 70 degrees Fahrenheit January 14: 69 degrees Fahrenheit January 15: 69.7 degrees Fahrenheit January 16: 71.3 degrees Fahrenheit January 18: 69 degrees Fahrenheit January 19: 68 degrees Fahrenheit January 20: 69 degrees Fahrenheit January 21: 70 degrees Fahrenheit January 22: 71.8, 71 degrees Fahrenheit January 26-28: 72, 68.5 degrees Fahrenheit January 29: 71.5 degrees Fahrenheit January 30: 70.9 degrees Fahrenheit February 2: 72 degrees Fahrenheit February 3-4: 65 degrees Fahrenheit February 5: 67 degrees Fahrenheit February 6: 72 degrees Fahrenheit February 8, 10: 72 degrees Fahrenheit February 11: 71 degrees Fahrenheit February 12-13, 15: 72 degrees Fahrenheit February 16: 70 degrees Fahrenheit February 17-18, 22: 72 degrees Fahrenheit February 23: 71 degrees Fahrenheit February 24-26: 72 degrees Fahrenheit February 28: 69 degrees Fahrenheit March 1: 72 degrees Fahrenheit March 3: 70 degrees Fahrenheit March 6: 72 degrees Fahrenheit March 8: 70 degrees Fahrenheit March 9: 72 degrees Fahrenheit March 10: 71 degrees Fahrenheit March 13, 15-16: 72 degrees Fahrenheit March 18: 71 degrees Fahrenheit March 19: 70 degrees Fahrenheit March 20: 72 degrees Fahrenheit March 22: 71 degrees Fahrenheit March 23: 70 degrees Fahrenheit March 24: 71 degrees Fahrenheit March 25: 72, 69.9 degrees Fahrenheit March 26: 69, 70 degrees Fahrenheit March 27: 71.7, 72 degrees Fahrenheit March 29: 68 degrees Fahrenheit March 30: 72 degrees Fahrenheit March 31: 71 degrees Fahrenheit April 1-2: 72 degrees Fahrenheit April 3: 70 degrees Fahrenheit April 5-7: 72 degrees Fahrenheit April 7: 70 degrees Fahrenheit April 8: 71 degrees Fahrenheit April 9-10: 70 degrees Fahrenheit April 12: 71 degrees Fahrenheit April 13: 69 degrees Fahrenheit April 15: 71 degrees Fahrenheit April 16: 70 degrees Fahrenheit April 17: 69 degrees Fahrenheit April 20: 72 degrees Fahrenheit April 21: 69 degrees Fahrenheit April 22: 71 degrees Fahrenheit April 23, 26: 72 degrees Fahrenheit April 27: 71 degrees Fahrenheit April 28: 72 degrees Fahrenheit April 29: 69 degrees Fahrenheit April 30: 70 degrees Fahrenheit May 3: 71, 70 degrees Fahrenheit May 4: 71 degrees Fahrenheit May 5: 68 degrees Fahrenheit May 6: 72 degrees Fahrenheit May 7: 70 degrees Fahrenheit May 8: 72 degrees Fahrenheit May 10: 71 degrees Fahrenheit May 11: 69.8 degrees Fahrenheit May 13: 71 degrees Fahrenheit May 14, 19-20: 70 degrees Fahrenheit May 21: 69 degrees Fahrenheit May 22, 26: 72 degrees Fahrenheit June 4: 69 degrees Fahrenheit June 5, 7: 72 degrees Fahrenheit June 8: 67

degrees Fahrenheit June 9: 68 degrees Fahrenheit June 10: 72 degrees Fahrenheit June 11: 69 degrees Fahrenheit June 12: 68 degrees Fahrenheit June 14: 69 degrees Fahrenheit June 15: 67 degrees Fahrenheit June 16, 18-19: 69 degrees Fahrenheit June 21: 68 degrees Fahrenheit June 22: 70 degrees Fahrenheit June 23: 69 degrees Fahrenheit June 24-25: 70 degrees Fahrenheit June 26, 28: 69 degrees Fahrenheit June 29: 71 degrees Fahrenheit July 2: 67 degrees Fahrenheit July 3: 68 degrees Fahrenheit July 5: 72 degrees Fahrenheit July 9: 68 degrees Fahrenheit July 12: 69 degrees Fahrenheit July 16-17: 71 degrees Fahrenheit July 19: 72 degrees Fahrenheit July 21: 70 degrees Fahrenheit July 22: 68 degrees Fahrenheit July 23: 66 degrees Fahrenheit July 24: 71 degrees Fahrenheit July 26: 70 degrees Fahrenheit July 27: 72 degrees Fahrenheit July 28: 70 degrees Fahrenheit July 29: 72 degrees Fahrenheit July 30: 68 degrees Fahrenheit July 31: 70 degrees Fahrenheit August 2: 69 degrees Fahrenheit August 4, 6: 72 degrees Fahrenheit August 7: 70 degrees Fahrenheit August 9, 11: 69 degrees Fahrenheit August 12: 68 degrees Fahrenheit August 13: 67 degrees Fahrenheit August 14: 71 degrees Fahrenheit August 16-17: 72 degrees Fahrenheit August 18: 71 degrees Fahrenheit August 19: 68 degrees Fahrenheit August 20: 72 degrees Fahrenheit August 21: 71 degrees Fahrenheit August 23: 72 degrees Fahrenheit August 24: 70 degrees Fahrenheit August 25: 72 degrees Fahrenheit August 26: 71 degrees Fahrenheit August 27: 72 degrees Fahrenheit August 28: 71 degrees Fahrenheit August 30: 72 degrees Fahrenheit September 1 70 degrees Fahrenheit September 2-3: 69 degrees Fahrenheit September 7: 70 degrees Fahrenheit September 8: 70.8 degrees Fahrenheit September 11: 71.9 degrees Fahrenheit September 21: 68 degrees Fahrenheit September 22: 69.8 degrees Fahrenheit September 23: 68.6 degrees Fahrenheit September 24-25, 28: 69 degrees Fahrenheit September 27: 71 degrees Fahrenheit September 29: 72 degrees Fahrenheit September 30: 67 degrees Fahrenheit October 1: 72 degrees Fahrenheit October 2, 4: 70 degrees Fahrenheit October 5-6: 69 degrees Fahrenheit October 9, 13: 70 degrees Fahrenheit October 14: 69 degrees Fahrenheit October 15: 71 degrees Fahrenheit October 16, 18: 70 degrees Fahrenheit October 19-20: 71 degrees Fahrenheit October 21: 70 degrees Fahrenheit October 23: 71 degrees Fahrenheit October 25: 72 degrees Fahrenheit October 27: 71 degrees Fahrenheit October 28: 72 degrees Fahrenheit October 29: 70 degrees Fahrenheit November 1: 70 degrees Fahrenheit November 2: 71 degrees Fahrenheit November 5-6: 72 degrees Fahrenheit November 8: 70 degrees Fahrenheit November 9-10: 72 degrees Fahrenheit November 11: 70 degrees Fahrenheit November 12-13, 15: 71 degrees Fahrenheit November 15, 16: 72 degrees Fahrenheit November 17: 71 degrees Fahrenheit November 20: 69 degrees Fahrenheit November 22: 70 degrees Fahrenheit November 23: 72 degrees Fahrenheit November 24, 26, 29: 71 degrees Fahrenheit November 30: 70 degrees Fahrenheit December 1-4: 71 degrees Fahrenheit December 6: 72 degrees Fahrenheit December 7: 71 degrees Fahrenheit December 8-10: 70 degrees Fahrenheit December 11: 69 degrees Fahrenheit December 13-14: 70 degrees Fahrenheit December 15: 71 degrees Fahrenheit December 16: 70 degrees Fahrenheit December 18: 71 degrees Fahrenheit December 21: 70 degrees Fahrenheit December 22-24: 71 degrees Fahrenheit December 28: 70 degrees Fahrenheit December 29: 69 degrees Fahrenheit December 30-31: 70 degrees Fahrenheit 2022 January 3-5: 70 degrees Fahrenheit January 6-8: 72 degrees Fahrenheit January 9: 67.7 degrees Fahrenheit January 11: 72.5 degrees Fahrenheit January 12: 71 degrees Fahrenheit January 13: 69.2 degrees Fahrenheit January 14: 69.7 degrees Fahrenheit January 15: 67.7 degrees Fahrenheit January 17: 70.8 degrees Fahrenheit January 18: 67.2 degrees Fahrenheit January 19: 69.7 degrees Fahrenheit January 20: 69 degrees Fahrenheit January 21-22: 72 degrees Fahrenheit January 24: 63.2 degrees Fahrenheit January 26: 67 degrees Fahrenheit January 27: 70 degrees Fahrenheit January 28: 71.3 degrees Fahrenheit January 29: 70.3 degrees Fahrenheit January 31: 67 degrees Fahrenheit February 1: 66.7 degrees Fahrenheit

February 2: 69 degrees Fahrenheit February 3: 68 degrees Fahrenheit February 4: 71.4 degrees Fahrenheit February 5: 72 degrees Fahrenheit February 7: 69.2 degrees Fahrenheit February 8: 70 degrees Fahrenheit February 9-10: 69 degrees Fahrenheit February 11: 70 degrees Fahrenheit February 12, 14: 71 degrees Fahrenheit February 15: 69 degrees Fahrenheit February 16-18: 71 degrees Fahrenheit February 21-23: 70 degrees Fahrenheit February 25: 69 degrees Fahrenheit February 26, 28: 70 degrees Fahrenheit March 2-3: 71 degrees Fahrenheit March 4: 70 degrees Fahrenheit March 5: 72 degrees Fahrenheit March 7: 68 degrees Fahrenheit March 8: 71 degrees Fahrenheit March 9: 69 degrees Fahrenheit March 14: 71.4 degrees Fahrenheit March 15: 70 degrees Fahrenheit March 16: 69 degrees Fahrenheit March 17: 72.3 degrees Fahrenheit March 23: 69.1 degrees Fahrenheit March 24: 67.9 degrees Fahrenheit March 25: 72.1 degrees Fahrenheit March 26: 72 degrees Fahrenheit March 28: 71.8 degrees Fahrenheit On 03/29/22 at 11:25 a.m., the co-director stated the refrigerator was out of range due to the need for defrosting, and the refrigerator thermostat had been adjusted too much. She also stated she thought 68-70 degrees Fahrenheit was room temperature and was unaware the laboratory needed to refer to the Insignia Rh view box user & service manual for the operating ambient temperature range to determine the room temperature range.