

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0952088	(X3) Date Survey Completed 04/07/2021
Name of Provider or Supplier Womens Center Of Hyde Park Llc	Street Address, City, State 4602 N Nebraska 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 Women's Center of Hyde Park, Inc. on 04/07/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review of the CMS 209 Laboratory Personnel Report, laboratory procedure manual, and American Association of Bioanalysts (AAB) proficiency testing attestation records for Immunohematology and interview with Testing Personnel #A, the laboratory failed to have 1 testing personnel (#A) out 2 testing personnel (#A and #B) rotate through the testing of proficiency for Immunohematology testing for two out of two (2019-2021) years reviewed. Findings included: Record review of the CMS 209 Laboratory Personnel Report signed by the Laboratory Director on 04/06/21 showed the laboratory had 2 testing personnel (#A and #B). Record review of the laboratory's manual (signed by the Laboratory Director on 01/01/21) revealed "Section IX Laboratory Quality Assurance Proficiency Testing " procedure that stated "Proficiency testing samples are tested, to the extent possible, exactly like patient specimens, i. e. the same number of times and using the same personnel and methods as for patient testing." Record review of the AAB Immunohematology (D (rh) typing) proficiency testing records revealed that Testing Personnel #B had signed the attestation statement for 6 of 6 proficiency testing events (1st, 2nd, #3rd Event 2019, 1st and 3rd Event 2020, and 1st Event 2021). Interview on 04/07/2021 at 11:25 AM with Testing Personnel #A revealed she had performed</p>

patient testing but had not performed AAB Immunohematology, D (rho) typing, proficiency testing for 2019-2021.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on interview with Testing Personnel #A and review of proficiency testing records and the procedure manual, the laboratory failed to maintain the Immunohematology proficiency testing result reports for 4 (1st, 2nd, and 3rd Events 2019 and 1st Event 2020) out of 5 testing events reviewed (2019 1st, 2nd, 3rd Events, and 2020 1st and 3rd Events). Findings included: Record review of American Association of Bioanalysts (AAB) proficiency testing documentation revealed there the laboratory had not retained the Immunohematology, D (rho) typing, proficiency testing results report for the 2019 1st , 2nd and 3rd Event and 2020 1st Event. Record review of the laboratory's procedure manual revealed that the "Section IX Laboratory Quality Assurance Proficiency Testing" stated "Proficiency Testing results are reviewed and retained for a period of 7 years." Interview on 04/07/2021 at 11:20 AM. with Testing Personnel #A revealed the laboratory had moved, and she could not find the AAB Immunohematology proficiency testing result reports for these events.

D2155

ABO GROUP AND D(RHO) TYPING
CFR(s): 493.859(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on American Association of Bioanalysts (AAB) proficiency testing record review and interview with Testing Personnel #A, the laboratory failed to notify AAB proficiency testing that the laboratory was closed which resulted in a score of zero percent (0%) for the Immunohematology analyte D (Rho) Typing for one event (2nd event in 2020) of seven events reviewed (1st, 2nd, #3rd Event 2019, 1st, 2nd, and 3rd

Event 2020, and 1st Event 2021). Findings included: Review of the American Association of Bioanalysts (AAB) records for Immunohematology for Quarter 2 2020 showed the laboratory received a score of "0.0 NR" (Not Reported to AAB) for the Immunohematology analyte D(Rho) Typing. Interview on 04/07/2020 at 11:30 AM with Testing Personnel #A revealed the laboratory was closed during the AAB Immunohematology 2020 2nd Event, and she did not know the laboratory needed to notify AAB that the laboratory closed while moving to another location.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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.

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 and the refrigerator temperature was out of range for 64 days out of of 375 days reviewed (February 2019 - April 6, 2021). Findings included: Record review of the " Lab Log - Women's Center of Hyde Park" revealed that the acceptable temperature range for room temperature was 68- 70 degrees Fahrenheit (F) and the refrigerator temperature acceptable range was 34- 46 F. Record review of the "Lab Log - Women's Center of Hyde Park" revealed that the room temperatures and refrigerator temperatures were out of range with no corrective action for the following dates: Room Temperatures: 1. February 12, 2019: documented temperature of "78 F" 2. February 21, 2019: documented temperature of "76 F" 3. March 6, 2019: documented temperature of "67 F" 4. April 5,, 2019: documented temperature of "76 F" 5. April 6, 2019: documented temperature of "76 F" 6. April 23, 2019: documented temperature of "76 F" 7. May 2 2019: documented temperature of "77 F" 8. May 7, 2019: documented temperature of "79 F" 9. May 9, 2019: documented temperature of "76 F" 10. May 14, 2019: documented temperature of "79 F" 11. May 28, 2019: documented temperature of "76 F" 12. June 1, 2019: documented temperature of "76 F" 13. June 7, 2019: documented temperature of "76 F" 14. June 11, 2019: documented temperature of "76 F" 15. June 13 2019: documented temperature of "76 F" 16. June 15, 2019: documented temperature of "76 F" 17. June 20, 2019: documented temperature of "76 F" 18. June 22, 2019: documented temperature of "76 F" 19. June 27, 2019: documented temperature of "76 F" 20. June 28, 2019: documented temperature of "76 F" 21. July 2, 2019: documented temperature of "76 F" 22. July 6, 2019: documented temperature of "77 F" 23. July 30, 2019: documented temperature of "78 F" 24. August 7, 2019: documented temperature of "76 F" 25. August 8, 2019: documented temperature of "76 F" 26. August 10, 2019: documented temperature of "77 F" 27. August 15, 2019: documented temperature of "78 F" 28. August 16, 2019: documented temperature of "77 F" 29. August 17, 2019: documented temperature of "76 F" 30. August 21, 2019: documented temperature of "76 F" 31. August 22, 2019: documented temperature of "80 F" 32. August 23, 2019: documented temperature of "80 F" 33. August 24, 2019:

documented temperature of "76 F" 34. August 27, 2019: documented temperature of "77 F" 35. September 11, 2019: documented temperature of "76 F" 36. September 12, 2019: documented temperature of "76 F" 37. September 17, 2019: documented temperature of "76 F" 38. September 18, 2019: documented temperature of "78 F" 39. October 1, 2019: documented temperature of "77 F" 40. October 4, 2019: documented temperature of "76 F" 41. October 5, 2019: documented temperature of "77 F" 42. November 14, 2019: documented temperature of "77 F" 43. November 16, 2019: documented temperature of "77 F" 44. November 27, 2019: documented temperature of "77 F" 45. December 10, 2019: documented temperature of "78 F" 46. December 11, 2019: documented temperature of "77 F" 47. December 12, 2019: documented temperature of "77 F" 48. February 12, 2020: documented temperature of "76 F" 49. February 18, 2020: documented temperature of "76 F" 50. September 12, 2020: documented temperature of "76 F" 51. September 30, 2020: documented temperature of "78 F" 52. October 9, 2020: documented temperature of "76 F" 53. October 14, 2020: documented temperature of "77 F" 54. October 15, 2020: documented temperature of "76 F" 55. October 29, 2020: documented temperature of "77 F" 56. November 11, 2020: documented temperature of "78 F" 57. November 27, 2020: documented temperature of "76 F" 58. December 23, 2020: documented temperature of "66 F" 59. January 16, 2021: documented temperature of "65 F" 60. January 19, 2021: documented temperature of "63 F" 61. January 21, 2021: documented temperature of "65 F" 62. January 22, 2021: documented temperature of "66 F" 63. February 2, 2021: documented temperature of "66 F" 64. February 20, 2021: documented temperature of "66 F" Refrigerator temperatures: 1. March 9, 2019: documented temperature of "32 F" 2. March 19, 2019: documented temperature of "32 F" 3. March 30, 2019: documented temperature of "32 F" 4. April 5, 2019: documented temperature of "32 F" 5. April 9, 2019: documented temperature of "32 F" 6. April 12, 2019: documented temperature of "32 F" 7. April 20, 2019: documented temperature of "32 F" 8. April 23, 2019: documented temperature of "32 F" 9. April 25, 2019: documented temperature of "32 F" 10. May 7, 2019: documented temperature of "32 F" 11. June 14, 2019: documented temperature of "32 F" 12. June 22, 2019: documented temperature of "32 F" 13. July 6, 2019: documented temperature of "32 F" 14. July 12, 2019: documented temperature of "30 F" 15. July 13, 2019: documented temperature of "30 F" 16. July 25, 2019: documented temperature of "32 F" 17. July 30, 2019: documented temperature of "32 F" 18. August 1, 2019: documented temperature of "32 F" 19. August 7, 2019: documented temperature of "32 F" 20. August 8, 2019: documented temperature of "32 F" 21. August 23, 2019: documented temperature of "32 F" 22. August 27, 2019: documented temperature of "30 F" 23. August 29, 2019: documented temperature of "28 F" 24. August 30, 2019: documented temperature of "32 F" 25. August 31, 2019: documented temperature of "32 F" 26. September 11, 2019: documented temperature of "32 F" 27. September 12, 2019: documented temperature of "32 F" 28. September 13, 2019: documented temperature of "32 F" 29. September 14, 2019: documented temperature of "32 F" 30. September 25, 2019: documented temperature of "32 F" 31. September 27, 2019: documented temperature of "32 F" 32. October 12, 2019: documented temperature of "32 F" 33. October 17, 2019: documented temperature of "32 F" 34. November 5, 2019: documented temperature of "32 F" 35. November 6, 2019: documented temperature of "32 F" 36. November 19, 2019: documented temperature of "32 F" 37. November 21, 2019: documented temperature of "32 F" 38. November 26, 2019: documented temperature of "32 F" 39. December 10, 2019: documented temperature of "32 F" 40. December 26, 2019: documented temperature of "32 F" 41. February 5, 2020: documented temperature of "32 F" 42. February 7, 2020: documented temperature of "32 F" 43. February 19 2020: documented temperature of "32 F" 44. February 26, 2020: documented temperature of "32 F" 45.

February 27, 2020: documented temperature of "32 F" 46. February 28, 2020: documented temperature of "32 F" 47. March 6, 2020: documented temperature of "32 F" 48. March 10, 2020: documented temperature of "32 F" 49. March 12, 2020: documented temperature of "32 F" 50. March 14, 2020: documented temperature of "32 F" 51. March 18, 2020: documented temperature of "32 F" 52. September 10, 2020: documented temperature of "32 F" 53. September 16, 2020: documented temperature of "32 F" 54. September 18, 2020: documented temperature of "32 F" 55. September 24, 2020: documented temperature of "32 F" 56. October 5 2020: documented temperature of "32 F" 57. October 9 2020: documented temperature of "32 F" 58. October 22 2020: documented temperature of "32 F" 59. October 23 2020: documented temperature of "32 F" 60. October 30 2020: documented temperature of "32 F" 61. November 2, 2020: documented temperature of "32 F" 62. November 5, 2020: documented temperature of "32 F" 63. November 19, 2020: documented temperature of "32 F" 64. January 8, 2021: documented temperature of "32 F" Interview on 04/07/21 at 11:55 AM with Testing Personnel #A revealed she did not know temperatures had been out of range so she had not performed corrective action.