

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0697355	(X3) Date Survey Completed 06/03/2021
Name of Provider or Supplier G Alexander Carden Md Pa & David W Dodson Md Pa	Street Address, City, State 1411 N Flagler Dr Ste 7900, 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 CLIA recertification survey was conducted at G Alexander Carden MD PA & David W Dodson MD PA on 6/3/21. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform competency assessments on two (#A and #C) out of two Testing Personnel (#A and #C) for the years 2019 and 2020. The findings included: A review of the CMS 209 Laboratory Personnel Report revealed Staff #A and #C worked at the laboratory as Testing Personnel (TP). A review of personnel records from 2019 - 2020 revealed no competency evaluations were found for TP #A and TP #C. A review of the facility procedure manual section "Performance/Competency Testing" revealed, "The purpose of the testing is to assess the qualifications and performance of the laboratory testing staff on an annual basis." In an interview, on 6/3/21 at 10:30 a.m., Testing Personnel #A stated she did not know the laboratory was to complete competency evaluations for herself or TP #C and added the consultant had retired.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform verification of quality controls for two out of two years (2019-2020). The findings included: Verification of quality controls documentation was not available at the time of survey. Review of the facility procedure manual section "Quality Control" revealed "For new controls or new control lots, the mean of each assay/instrument combination is established by running the new control for a minimum of two weeks (one week with 5 replicates of hematology controls)." In an interview, on 6/3/21 at 11:15 a.m., Testing Personnel #A stated she did not know that she was to perform verification of quality control verifications.

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 interview with Testing Personnel #A, the laboratory failed to document corrective action when the freezer temperatures, where the chemistry and immunology controls and chemistry and immunology calibrators were stored, were out of range for 132 out of 324 days from January 2020 to June 3, 2021. The findings included: Record review of package inserts for "Liquid Assayed Multiquel Levels 1, 2, and 3, Liquichek Immunoassay Plus Control Levels 1, 2, and 3, and Liquichek Tumor Marker Control Levels 1, 2, and 3" and Vitros calibrators revealed that the proper storage was less than - 20 degrees Celsius (C) The record review of the "Temperatures" logs showed the acceptable temperature range was less than -20 degrees C. The following temperatures were documented: 1. 01/02/2020: "-18 degrees C" 2. 01/03/2020: "-18 degrees C" 3. 01/06/2020: "-18 degrees C" 4. 01/07/2020: "-16 degrees C" 5. 01/08/2020: "-18 degrees C" 6. 01/17/2020: "-18 degrees C" 7. 01/22/2020: "-18 degrees C" 8. 01/23/2020: "-18 degrees C" 9. 01/24/2020: "-18 degrees C" 10. 01/28/2020: "-18 degrees C" 11. 01/29/2020: "-18 degrees C" 12. 01/31

/2020: "-18 degrees C" 13. 02/03/2020: "-18 degrees C" 14. 02/05/2020: "-18 degrees C" 15. 02/11/2020: "-18 degrees C" 16. 02/14/2020: "-18 degrees C" 17. 02/18/2020: "-18 degrees C" 18. 02/20/2020: "-18 degrees C" 19. 02/27/2020: "-18 degrees C" 20. 03/02/2020: "-18 degrees C" 21. 03/04/2020: "-18 degrees C" 22. 03/11/2020: "-18 degrees C" 23. 03/19/2020: "-18 degrees C" 24. 03/20/2020: "-18 degrees C" 25. 03/25/2020: "-18 degrees C" 26. 04/01/2020: "-18 degrees C" 27. 04/02/2020: "-18 degrees C" 28. 04/03/2020: "-18 degrees C" 29. 04/07/2020: "-18 degrees C" 30. 05/06/2020: "-18 degrees C" 31. 05/13/2020: "-18 degrees C" 32. 05/22/2020: "-18 degrees C" 33. 05/28/2020: "-18 degrees C" 34. 06/01/2020: "-18 degrees C" 35. 06/02/2020: "-18 degrees C" 36. 06/03/2020: "-17 degrees C" 37. 06/04/2020: "-18 degrees C" 38. 06/08/2020: "-18 degrees C" 39. 06/11/2020: "-18 degrees C" 40. 06/12/2020: "-18 degrees C" 41. 06/15/2020: "-18 degrees C" 42. 06/18/2020: "-18 degrees C" 43. 06/19/2020: "-18 degrees C" 44. 06/22/2020: "-18 degrees C" 45. 06/25/2020: "-18 degrees C" 46. 06/30/2020: "-18 degrees C" 47. 07/07/2020: "-18 degrees C" 48. 07/09/2020: "-18 degrees C" 49. 07/13/2020: "-18 degrees C" 50. 07/16/2020: "-18 degrees C" 51. 07/20/2020: "-18 degrees C" 52. 07/22/2020: "-18 degrees C" 53. 07/23/2020: "-18 degrees C" 54. 07/24/2020: "-16 degrees C" 55. 07/27/2020: "-18 degrees C" 56. 07/28/2020: "-18 degrees C" 57. 07/29/2020: "-18 degrees C" 58. 07/30/2020: "-16 degrees C" 59. 08/11/2020: "-18 degrees C" 60. 08/20/2020: "-18 degrees C" 61. 08/21/2020: "-18 degrees C" 62. 08/24/2020: "-18 degrees C" 63. 08/27/2020: "-18 degrees C" 64. 09/02/2020: "-18 degrees C" 65. 09/08/2020: "-18 degrees C" 66. 09/14/2020: "-18 degrees C" 67. 09/17/2020: "-18 degrees C" 68. 09/23/2020: "-18 degrees C" 69. 09/25/2020: "-18 degrees C" 70. 09/28/2020: "-18 degrees C" 71. 09/29/2020: "-18 degrees C" 72. 10/02/2020: "-18 degrees C" 73. 10/06/2020: "-18 degrees C" 74. 10/16/2020: "-18 degrees C" 75. 10/20/2020: "-18 degrees C" 76. 10/26/2020: "-18 degrees C" 77. 11/02/2020: "-18 degrees C" 78. 11/04/2020: "-18 degrees C" 79. 11/06/2020: "-18 degrees C" 80. 11/09/2020: "-18 degrees C" 81. 11/13/2020: "-18 degrees C" 82. 11/16/2020: "-18 degrees C" 83. 11/18/2020: "-18 degrees C" 84. 11/19/2020: "-16 degrees C" 85. 11/23/2020: "-18 degrees C" 86. 11/24/2020: "-18 degrees C" 87. 11/30/2020: "-18 degrees C" 88. 12/02/2020: "-16 degrees C" 89. 12/03/2020: "-18 degrees C" 90. 12/08/2020: "-18 degrees C" 91. 12/09/2020: "-18 degrees C" 92. 12/11/2020: "-18 degrees C" 93. 12/21/2020: "-18 degrees C" 94. 12/30/2020: "-18 degrees C" 95. 01/06/2020: "-18 degrees C" 96. 01/07/2020: "-18 degrees C" 97. 01/11/2020: "-18 degrees C" 98. 01/13/2020: "-18 degrees C" 99. 01/14/2020: "-18 degrees C" 100. 01/15/2020: "-18 degrees C" 101. 01/18/2020: "-18 degrees C" 102. 01/19/2020: "-18 degrees C" 103. 01/22/2020: "-18 degrees C" 104. 01/26/2020: "-18 degrees C" 105. 01/26/2020: "-18 degrees C" 106. 02/01/2020: "-18 degrees C" 107. 02/04/2020: "-18 degrees C" 108. 02/09/2020: "-18 degrees C" 109. 02/17/2020: "-18 degrees C" 110. 02/22/2020: "-18 degrees C" 111. 02/24/2020: "-18 degrees C" 112. 03/02/2020: "-18 degrees C" 113. 03/04/2020: "-18 degrees C" 114. 03/09/2020: "-18 degrees C" 115. 03/18/2020: "-18 degrees C" 116. 03/22/2020: "-18 degrees C" 117. 03/24/2020: "-18 degrees C" 118. 03/30/2020: "-18 degrees C" 119. 04/12/2020: "-18 degrees C" 120. 05/03/2020: "-18 degrees C" 121. 05/05/2020: "-18 degrees C" 122. 05/10/2020: "-18 degrees C" 123. 05/13/2020: "-18 degrees C" 124. 05/18/2020: "-18 degrees C" 125. 05/19/2020: "-18 degrees C" 126. 05/20/2020: "-16 degrees C" 127. 05/21/2020: "-18 degrees C" 128. 05/25/2020: "-18 degrees C" 129. 05/26/2020: "-18 degrees C" 130. 05/27/2020: "-18 degrees C" 131. 05/28/2020: "-16 degrees C" 132. 06/01/2020: "-16 degrees C" In an interview, on 6/3/21 at 10:45 a.m., Testing Personnel #A stated the Laboratory Director tried to find a refrigerator that did not have a defrost cycle.