

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0270159	(X3) Date Survey Completed 09/23/2022
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 1264 Metropolitan Blvd #B100, Tallahassee, 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	A recertification survey was conducted on September 22 and 23, 2022. Laboratory Corporation of America Clinical Laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the Laboratory Manager, the laboratory failed to properly label a plastic container of blue liquid in the hematology department. Findings include: 1. During the laboratory tour at 8:15 a.m. on 9/23/2022, a plastic container of blue liquid was observed in the hematology area, having only a date written on the label. 2. During interview with the Laboratory Manager on 9/23 /2022 at 11:00 a.m., it was confirmed the plastic container of blue liquid was used for Wright Stains and did not have a label to include the identity, preparation date and expiration date.</p>
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</p>

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 temperature record review and interview with the Laboratory Manager, the laboratory failed to document corrective actions for temperatures out of acceptable range for the heat block and three freezers during 2021. Findings include: Record review of the "Heat Block" logs showed the acceptable temperature range as "36 - 38 Celsius (C)." The following dates had temperatures out of acceptable range with no corrective action documented: 1. January 10, 2021: documented temperature of "35.1 C" 2. January 13, 2021: documented temperature of "34.5 C" 3. January 14, 2021: documented temperature of "35.1 C" 4. January 15, 2021: documented temperature of "35.1 C" 5. January 17, 2021: documented temperature of "34.5 C" 6. January 18, 2021: documented temperature of "34.9 C" 7. January 19, 2021: documented temperature of "35.1 C" 8. January 21, 2021: documented temperature of "35.8 C" 9. January 22, 2021: documented temperature of "35.2 C" 10. January 23, 2021: documented temperature of "35.0 C" 11. January 25, 2021: documented temperature of "35.4 C" 12. January 26, 2021: documented temperature of "35.9 C" 13. January 29, 2021: documented temperature of "35.1 C" 14. February 9, 2021: documented temperature of "35.5 C" 15. February 11, 2021: documented temperature of "35.8 C" 16. February 14, 2021: documented temperature of " 35.0 C" 17. February 16, 2021: documented temperature of "35.2 C" 18. February 22, 2021: documented temperature of "35.9 C" 19. February 26, 2021: documented temperature of "35.5 C" 20. March 1, 2021: documented temperature of "35.5 C" 21. March 2, 2021: documented temperature of "35.4 C" 22. March 3, 2021: documented temperature of "35.9 C" 23. March 14, 2021: documented temperature of "35.2 C" 24. March 19, 2021: documented temperature of "35.6 C" 25. March 21, 2021: documented temperature of "35.2 C" 26. March 24, 2021: documented temperature of "35.8 C" 27. March 25, 2021: documented temperature of "35.8 C" 28. March 28, 2021: documented temperature of "34.1 C" 29. April 18, 2021: documented temperature of "35.3 C" 30. April 25, 2021: documented temperature of "35.0 C" 31. April 30, 2021: documented temperature of "35.2 C" 32. May 10, 2021: documented temperature of "35.5 C" 33. May 18, 2021: documented temperature of "33.5 C" 34. May 19, 2021: documented temperature of "34.2 C" 35. May 20, 2021: documented temperature of "34.5 C" 36. May 24, 2021: documented temperature of "34.9 C" 37. May 25, 2021: documented temperature of " 35.1 C" 38. May 26, 2021: documented temperature of "34.9 C" 39. May 27, 2021: documented temperature of "35.6 C" 40. May 29, 2021: documented temperature of "35.6 C" 41. May 30, 2021: documented temperature of "31.2 C" 42. June 16, 2021: documented temperature of "38.1 C" 43. June 19, 2021: documented temperature of "38.2 C" 44. July 4, 2021: documented temperature of "38.2 C" 45. July 25, 2021: documented temperature of "38.1 C" 46. October 3, 2021: documented temperature of "39.0 C" 47. November 13, 2021: documented temperature of "40.6 C" 48. November 14, 2021: documented temperature of "41.3 C" 49. November 15 documented temperature of "41.0 C" 50. November 23 documented temperature of "38.6 C" Record review of the "Magic Chef Freezer Serial Number 1905000175" logs showed the acceptable temperature range as "-18 to -25 Celsius (C)." The following dates had temperatures out of the acceptable range with no corrective action documented: 1. January 4, 2021: documented temperature of "-15.7 C" 2. January 11, 2021: documented temperature of "-16.1 C" 3. January 14, 2021: documented

temperature of "-16.0 C" 4. January 15, 2021: documented temperature of "-17.8 C" 5. January 18, 2021: documented temperature of "-14.4 C" 6. January 19, 2021: documented temperature of "-15.2 C" 7. January 20, 2021: documented temperature of "-13.1 C" 8. January 21, 2021: documented temperature of "-13.5 C" 9. January 22, 2021: documented temperature of "-17.8 C" 10. January 25, 2021: documented temperature of "-17.5 C" 11. January 27, 2021: documented temperature of "-17.5 C" 12. February 1, 2021: documented temperature of "-14.1 C" 13. February 2, 2021: documented temperature of "-15.3 C" 14. February 3, 2021: documented temperature of "-17.3 C" 15. February 4, 2021: documented temperature of "-15.9 C" 16. February 5, 2021: documented temperature of "-16.3 C" 17. February 8, 2021: documented temperature of "-17.1 C" 18. February 9, 2021: documented temperature of "-12.2 C" 19. February 10, 2021: documented temperature of "-17.1 C" 20. February 11, 2021: documented temperature of "-13.9 C" 21. February 12, 2021: documented temperature of "-13.6 C" 22. February 13, 2021: documented temperature of "-17.0 C" 23. February 14, 2021: documented temperature of "-17.8 C" 24. February 15, 2021: documented temperature of "-15.3 C" 25. February 17, 2021: documented temperature of "-13.1 C" 26. February 21, 2021: no temperature documented 27. February 22, 2021: documented temperature of "-15.8 C" 28. February 23, 2021: documented temperature of "-15.9 C" 29. February 24, 2021: documented temperature of "-16.0 C" 30. February 25 through 29, 2021: no temperature documented 31. March 1, 2021: documented temperature of "-14.0 C" 32. March 2, 2021: documented temperature of "-14.2 C" 33. March 3, 2021: documented temperature of "-11.3 C" 34. March 4, 2021: documented temperature of "-11.2 C" 35. March 5, 2021: documented temperature of "-12.5 C" 36. March 6, 2021: documented temperature of "-16.5 C" 37. March 7, 2021: documented temperature of "-16.0 C" 38. March 8, 2021: documented temperature of "-15.0 C" 39. March 9, 2021: documented temperature of "-15.0 C" 40. March 10, 2021: documented temperature of "-14.0 C" 41. March 11, 2021: documented temperature of "-15.6 C" 42. March 12, 2021: documented temperature of "-16.2 C" 43. March 15, 2021: documented temperature of "-17.9 C" 44. March 16, 2021: documented temperature of "-17.7 C" 45. March 17, 2021: documented temperature of "-17.2 C" 46. March 18, 2021: documented temperature of "-17.5 C" 47. March 19, 2021: documented temperature of "-17.3 C" 48. March 29, 2021: documented temperature of "-17.3 C" 49. March 30, 2021: documented temperature of "-17.5 C" 50. March 31, 2021: documented temperature of "-17.2 C" 51. April 1, 2021: documented temperature of "-17.5 C" 52. April 2, 2021: documented temperature of "-17.7 C" 53. April 4, 2021: documented temperature of "-17.0 C" 54. April 6, 2021: documented temperature of "-17.9 C" 55. April 9, 2021: documented temperature of "-17.9 C" 56. April 10, 2021: documented temperature of "-17.1 C" 57. April 11, 2021: documented temperature of "-17.6 C" 58. April 12, 2021: documented temperature of "-17.1 C" Record review of the "Magic Chef Freezer Serial Number 1902000280" logs showed the acceptable temperature range as "-20 to -25 Celsius (C)." The following dates had temperatures out of range with no corrective action documented: 1. January 5, 2021: documented temperature of "-17.5 C" 2. January 12, 2021: documented temperature of "-17.9 C" 3. January 14, 2021: documented temperature of "-16.9 C" 4. January 18, 2021: documented temperature of "-17.2 C" 5. January 20, 2021: documented temperature of "-17.5 C" 6. January 21, 2021: documented temperature of "-15.0 C" 7. January 22, 2021: documented temperature of "-13.6 C" 8. January 25, 2021: documented temperature of "-17.4 C" 9. January 26, 2021: documented temperature of "-17.6 C" 10. January 29, 2021: documented temperature of "-18.6 C" 11. January 30, 2021: documented temperature of "-18.6 C" 12. January 31, 2021: documented temperature of "-18.5 C" 13. February 2, 2021: documented temperature of "-17.8 C" 14. February 9, 2021: documented temperature of "-18.6 C" 15. February 11, 2021: documented temperature of "-16.5 C" 16.

February 18, 2021: documented temperature of "-17.7 C" 17. February 25, 2021: documented temperature of "-19.7 C" 18. March 1, 2021: documented temperature of "-17.8 C" 19. March 2, 2021: documented temperature of "-18.6 C" 20. March 3, 2021: documented temperature of "-16.8 C" 21. March 4, 2021: documented temperature of "-17.9 C" 22. March 5, 2021: documented temperature of "-16.6 C" 23. March 6, 2021: documented temperature of "-17.7 C" 24. March 7, 2021: documented temperature of "-16.9 C" 25. March 8, 2021: documented temperature of "-12.1 C" 26. March 9, 2021: documented temperature of "-10.9 C" 27. March 11, 2021: documented temperature of "-16.9 C" 28. March 12, 2021: documented temperature of "-16.0 C" 29. March 15, 2021: documented temperature of "-17.5 C" 30. March 16, 2021: documented temperature of "-16.9 C" 31. March 17, 2021: documented temperature of "-17.7 C" 32. March 18, 2021: documented temperature of "-16.3 C" 33. March 19, 2021: documented temperature of "-17.4 C" 34. March 20, 2021: documented temperature of "-16.8 C" 35. March 21, 2021: documented temperature of "-17.2 C" 36. March 22, 2021: documented temperature of "-17.3 C" 37. March 23, 2021: documented temperature of "-17.3 C" 38. March 24, 2021: documented temperature of "-17.1 C" 39. March 25, 2021: documented temperature of "-16.4 C" 40. March 26, 2021: documented temperature of "-17.2 C" 41. March 27, 2021: documented temperature of "-18.0 C" 42. March 28, 2021: documented temperature of "-18.2 C" 43. March 29, 2021: documented temperature of "-18.0 C" 44. March 30, 2021: documented temperature of "-18.4 C" 45. March 31, 2021: documented temperature of "-18.0 C" 46. April 1, 2021: documented temperature of "-18.0 C" 47. April 2, 2021: documented temperature of "-18.9 C" 48. April 3, 2021: documented temperature of "-18.0 C" 49. April 4, 2021: documented temperature of "-17.8 C" 50. April 5, 2021: documented temperature of "-19.6 C" 51. April 9, 2021: documented temperature of "-18.1 C" 52. April 14, 2021: documented temperature of "-18.4 C" 53. April 15, 2021: documented temperature of "-18.1 C" 54. April 16, 2021: documented temperature of "-18.0 C" 55. April 17, 2021: documented temperature of "-19.2 C" 56. April 18, 2021: documented temperature of "-19.0 C" 57. April 19, 2021: documented temperature of "-19.3 C" 58. April 20, 2021: documented temperature of "-18.4 C" 59. April 21, 2021: documented temperature of "-19.2 C" 60. April 24, 2021: documented temperature of "-19.6 C" 61. April 28, 2021: documented temperature of "-19.1 C" 62. April 29, 2021: documented temperature of "-19.6 C" 63. May 7, 2021: documented temperature of "-17.9 C" 64. May 9, 2021: documented temperature of "-19.0 C" 65. May 10, 2021: "documented temperature of -19.0 C" 66. May 11, 2021: documented temperature of "-18.3 C" 67. May 12, 2021: documented temperature of "-18.4 C" 68. May 15, 2021: documented temperature of "-19.5 C" 69. May 16, 2021: documented temperature of "-13.1 C" 70. May 17, 2021: documented temperature of "-18.4 C" 71. May 18, 2021: documented temperature of "-18.5 C" 72. May 20, 2021: documented temperature of "-17.9 C" 73. May 21, 2021: documented temperature of "-18.4 C" 74. May 22, 2021: documented temperature of "-19.0 C" 75. May 23, 2021: documented temperature of "-18.0 C" 76. May 24, 2021: documented temperature of "-18.3 C" 77. May 27, 2021: documented temperature of "-19.1 C" 78. June 1, 2021: documented temperature of "-18.9 C" 79. June 2, 2021: documented temperature of "-19.2 C" 80. June 4, 2021: documented temperature of "-17.2 C" 81. June 5, 2021: documented temperature of "-17.3 C" 82. June 7, 2021: documented temperature of "-18.4 C" 83. June 9, 2021: documented temperature of "-19.5 C" 84. June 10, 2021: documented temperature of "-18.6 C" 85. June 11, 2021: documented temperature of "-18.3 C" 86. June 12, 2021: documented temperature of "-18.0 C" 87. June 13, 2021: documented temperature of "-18.7 C" 88. June 15, 2021: documented temperature of "-18.3 C" 89. June 16, 2021: documented temperature of "-18.1 C" 90. June 17, 2021: documented temperature of "-18.6 C" 91. June 18, 2021: documented temperature of "-17.6 C" 92. June 19, 2021: documented temperature of "-17.6 C" 93. June 20, 2021: documented

temperature of "-17.9 C" 94. June 21, 2021: documented temperature of "-19.1 C" 95. June 22, 2021: documented temperature of "-18.7 C" 96. June 23, 2021: documented temperature of "-18.1 C" 97. June 24, 2021: documented temperature of "-18.3 C" 98. June 25, 2021: documented temperature of "-17.6 C" 99. June 26, 2021: documented temperature of "-19.4 C" 100. June 27, 2021: documented temperature of "-19.0 C" 101. June 28, 2021: documented temperature of "-19.4 C" 102. June 29, 2021: documented temperature of "-18.0 C" 103. June 30, 2021: documented temperature of "-17.4 C" 104. July 1, 2021: documented temperature of "-19.0 C" 105. July 2, 2021: documented temperature of "-19.0 C" 106. July 3, 2021: documented temperature of "-18.2 C" 107. July 5, 2021: documented temperature of "-19.2 C" 108. July 6, 2021: documented temperature of "-19.0 C" 109. July 7, 2021: documented temperature of "-19.0 C" 110. July 8, 2021: documented temperature of "-19.0 C" 111. July 9, 2021: documented temperature of "-19.2 C" 112. July 11, 2021: documented temperature of "-17.5 C" 113. July 12, 2021: documented temperature of "-18.0 C" 114. July 15, 2021: documented temperature of "-19.0 C" 115. July 16, 2021: documented temperature of "-18.0 C" 116. July 17, 2021: documented temperature of "-18.0 C" 117. July 18, 2021: documented temperature of "-19.7 C" 118. July 20, 2021: documented temperature of "-19.6 C" 119. July 21, 2021: documented temperature of "-17.7 C" 120. July 22, 2021: documented temperature of "-17.7 C" 121. July 23, 2021: documented temperature of "-17.1 C" 122. July 24, 2021: documented temperature of "-18.1 C" 123. July 25, 2021: documented temperature of "-18.9 C" 124. July 26, 2021: documented temperature of "-18.0 C" 125. July 27, 2021: documented temperature of "-16.9 C" 126. July 28, 2021: documented temperature of "-17.3 C" 127. July 29, 2021: documented temperature of "-18.4 C" 128. July 30, 2021: documented temperature of "-17.7 C" 129. July 31, 2021: documented temperature of "-17.5 C" 130. August 1, 2021: documented temperature of "-17.0 C" 131. August 3, 2021: documented temperature of "-18.0 C" 132. August 4, 2021: documented temperature of "-18.1 C" 133. August 5, 2021: documented temperature of "-17.6 C" 134. August 6, 2021: documented temperature of "-19.0 C" 135. August 7, 2021: documented temperature of "-19.5 C" 136. August 10, 2021: documented temperature of "-17.5 C" 137. August 12, 2021: documented temperature of "-18.0 C" 138. August 13, 2021: documented temperature of "-18.0 C" 139. August 14, 2021: documented temperature of "-18.6 C" 140. August 15, 2021: documented temperature of "-18.6 C" 141. August 16, 2021: documented temperature of "-18.4 C" 142. August 18, 2021: documented temperature of "-18.6 C" 143. August 19, 2021: documented temperature of "-18.8 C" 144. August 20, 2021: documented temperature of "-18.1 C" 145. August 21, 2021: documented temperature of "-18.3 C" 146. August 23, 2021: documented temperature of "-19.6 C" 147. August 28, 2021: documented temperature of "-18.7 C" 148. August 29, 2021: documented temperature of "-18.6 C" 149. August 30, 2021: documented temperature of "-18.1 C" 150. August 31, 2021: documented temperature of "-18.2 C" 151. September 1, 2021: documented temperature of "-17.1 C" 152. September 4, 2021: documented temperature of "-19.3 C" 153. September 5, 2021: documented temperature of "-19.2 C" 154. September 6, 2021: documented temperature of "-19.6 C" 155. September 21, 2021: documented temperature of "-19.2 C" 156. September 23, 2021: documented temperature of "-19.3 C" 157. September 24, 2021: documented temperature of "-19.3 C" 158. September 26, 2021: documented temperature of "-18.9 C" 159. October 6, 2021: documented temperature of "-19.1 C" 160. October 19, 2021: documented temperature of "-19.0 C" 161. October 21, 2021: documented temperature of "-19.0 C" 162. October 23, 2021: documented temperature of "-19.2 C" 163. October 29, 2021: documented temperature of "-19.4 C" 164. November 4, 2021: documented temperature of "-18.4 C" 165. November 8, 2021: documented temperature of "-19.1 C" 166. November 9, 2021: documented temperature of "-18.0 C" 167. November 13, 2021: documented

temperature of "-16.9 C" 168. November 15, 2021: documented temperature of "-19.0 C" 169. November 20, 2021: documented temperature of "-19.8 C" 170. November 21, 2021: documented temperature of "-19.6 C" 171. December 5, 2021: documented temperature of "-19.3 C" 172. December 11, 2021: documented temperature of "-15.8 C" 173. December 19, 2021: no temperature documented 174. December 21, 2021: documented temperature of "-19.0 C" 175. December 22, 2021: documented temperature of "-19.2 C" 176. December 23, 2021: documented temperature of "-18.0 C" 177. December 27, 2021: documented temperature of "-19.0 C" 178. December 28, 2021: documented temperature of "-19.7 C" 179. December 29, 2021: documented temperature of "-18.6 C" 180. December 31, 2021: documented temperature of "-19.6 C" Record review of "Freezer Serial Number 210278078" logs showed the acceptable temperature range as " -18 to -21 Celsius (C)." The following dates had temperatures out of the acceptable range with no corrective action documented: 1. May 17, 2021: documented temperature of "-17.0 C" 2. May 19, 2021: documented temperature of "-17.0 C" 3. May 20, 2021: documented temperature of "-17.0 C" 4. June 10, 2021: documented temperature of "-23 C" 5. June 12, 2021: documented temperature of "-17.1 C" 6. June 30, 2021: documented temperature of "-16.0 C" 7. July 8, 2021: documented temperature of "-17.0 C" 8. July 24, 2021: documented temperature of "-17.5 C" 9. July 25, 2021: documented temperature of "-17.6 C" 10. August 7, 2021: documented temperature of "-16.3 C" 11. August 12, 2021: documented temperature of "-17.1 C" 12. August 18, 2021: documented temperature of "-17.9 C" 13. August 21, 2021: documented temperature of "-21.8 C" 14. August 23, 2021: documented temperature of "-24.0 C" 15. August 28, 2021: documented temperature of "-23.5 C" 16. August 29, 2021: documented temperature of "-22.5 C" 17. August 30, 2021: documented temperature of "-22.5 C" 18. September 4, 2021: documented temperature of "-21.1 C" 19. September 14, 2021: documented temperature of "-23.3 C" 20. September 25, 2021: documented temperature of "-21.2 C" 21. October 1, 2021: documented temperature of "-21.1 C" 22. October 6, 2021: documented temperature of "-26.1 C" 23. October 7, 2021: documented temperature of "-22.4 C" 24. October 22, 2021: documented temperature of "-17.0 C" 25. November 4, 2021: documented temperature of "-22.9 C" 26. November 16, 2021: documented temperature of "-21.4 C" 27. November 19, 2021: documented temperature of "-22.0 C" 28. November 22, 2021: documented temperature of "-22.0 C" 29. December 17, 2021: documented temperature of "-21.2 C" 30. December 26, 2021: documented temperature of "-16.5 C" Based on interview with the Laboratory Manager on 9/23 /2022 at 11:00 a.m., it was confirmed no corrective actions were documented for temperatures out of range on the heat block and three freezers.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 Based on record review and interview with the Laboratory Manager, the Technical Supervisor (TS) failed to sign annual competency assessments for 2 (#B and #C) out of 4 Testing Personnel (TP) for 2021 and 2022. Findings include: Record review of

annual competencies revealed the TS's signature was missing from forms for TP #B in 2022 and TP #C in 2021 and 2022. Interview with the Laboratory Manager on 9/23 /2022 at 11:00 a.m., confirmed the TS's signature was missing from annual competency forms for TP# B and TP #C.