Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0968944	06/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas, Pllc	1002 West Sam Houston Suite 4, Pharr, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, surveyor observation, review of the laboratory's room temperature records, and staff interview, it was revealed the laboratory failed to monitor the correct temperature range for reagents. The findings were: 1. Based on review of the manufacturer's instructions for the PTS Panels eGlu glucose test strips (PS-004580 E Rev. 3 02/19) under the section titled "Storage and Handling" revealed: "Test strips must be brought to room temperature 68-86F (20-30C) before using." 2. A review of the manufacturer's instructions for the PTS Panels Lipid Panel test strips (PS-002676 E Rev. 1 02/19) under the section titled "Storage and Handling" revealed: "Test strips must be brought to room temperature 68-86F (20-

	30C) before using." 3. Surveyor observation on 06/009/2021 at 1040 hours in the laboratory revealed 1 bottle of glucose test strips and 1 bottle of Lipid panels test strips out on the counter currently in use. 4. A review of the laboratory's room temperature records from December 2020 - May 2021 revealed the laboratory's defined acceptable temperature range was 64.4 - 77 degrees Fahrenheit. 5. Further review of the records revealed the following days where the documented temperatures was outside the manufacturer's required range for the test strips: a) December 2020 December 1 66F December 5 66F December 6 66F December 7 66F December 8 64F December 9 66F December 10 64F December 11 66F December 12 64F December 13 66F December 15 66F December 16 66F December 17 66F December 18 64F December 19 66F December 21 66F December 22 64F December 23 66F December 24 64F December 25 66F December 27 66F December 28 64F December 29 66F December 30 66F b) January 2021 January 2 66F January 3 66F January 4 66F January 15 66F January 17 66F January 18 66F January 24 66F c) February 2021 February 1 66F February 7 66F February 13 66F February 17 66F February 18 64F February 19 66F d) March 2021 March 1 66F March 9 66F March 10 66F March 11 64F March 12 66F March 17 66F March 21 66F March 27 66F March 28 66F e) April 2021 April 1 66F April 10 66F April 11 64F April 13 66F April 18 66F April 24 66F April 25 66F f) May 2021 May 1 66F May 4 66F May 17 66F May 26 66F May 27 66F 6. An interview with the laboratory director on 06/09/2021 at 1045 hours in the conference room - after her review of the records- confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's room temperature records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the room temperature was not within the laboratory's defined acceptable range. The findings were: 1. A review of the laboratory's room temperature records from December 2020 to May 2021 revealed the laboratory had a defined acceptable range for room temperature of 64.4 - 77 degrees Fahrenheit. 2. Further review of the records revealed the following days when the documented temperature was outside the acceptable range: a) December 2020 December 8 64F December 10 64F December 12 64F December 18 64F December 22 64F December 24 64F December 28 64F b) February 2021 February 18 64F c) March 2021 March 11 64F d) April 2021 April 11 64F 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. An interview with the laboratory director on 06/09/2021 at 1100 hours in the conference room confirmed the findings.