Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0908313	01/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas, Pllc	7013 South Cage Suite C, 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 representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, 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 recertification 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 the laboratory's CMS Form 209, review of manufacturer's instructions, laboratory personnel records, patient records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions to ensure 2 of 2 laboratory testing personnel were trained prior to patient testing using Quidel's Quickvue SARS-COV-2 test kit under Emergency Use Authorization (EUA). The findings included: 1. Review of the laboratory's submitted CMS Form 209 approved by the laboratory director on January 12, 2022 found the laboratory listed 2 testing persons that performed SARS-COV-2 patient testing. 2. Review of the manufacturer's instructions for the Quidel Quickvue SARS-COV-2 test kit under

	Conditions of Authorization for the laboratory and patient care, it stated, "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 3. Review of personnel records for the following 2 of testing persons (as listed on CMS Form 209) performing SARS-COV-2 did not have documentation of training as required by the manufacturer: Testing Personnel 1 Testing Personnel 2 4. The laboratory was asked to provide documentation of following the manufacturer's instructions to ensure testing persons were trained to perform SARS-COV-2 patient testing using the Quidel Quickvue test kit. No documentation was provided. 5. Review of laboratory records found that the laboratory performed a minimum of 324 SARS-COV-2 tests from October 1, 2021 to January 12, 2022 (the day of the survey). 6. An interview with the laboratory director on January 12, 2022 at 9:030 a.m. hours in the break room confirmed the findings. Upon her review of the records, she agreed there was no documentation of training records available for review. Key: SARS-COV-2 - Severe acute respiratory syndrome coronavirus 2 CMS - Centers for Medicare and Medicaid Services
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the Medonic M- Series User's Manual, a review of the laboratory's policies, review of patient records, and confirmed in laboratory personnel interview, the laboratory failed to follow its own policy for resolution of flags on eight of eight random CBC (complete blood count) results reviewed with flags from March 2021 to December 2021. The findings included: 1. A review of the Medonic M- Series User's Manual (Article no. 1504472, 02/2016) revealed the following flags: "BD, NM, OM, TM flags - Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 2. A review of the laboratory's policy titled 'Actions Protocol for WBC Differential FLAGS' approved by the laboratory director on January 5, 2021 stated the following: "If the provider does not normally need the specimen to be sent out to a Reference Lab - block out the auto WBC DIFF portion and then submit to provider, he will then make assessment of patient using only the hemogram." 3. Review of patient records found the following eight of eight patient samples from March 2021 to December 2021 for CBC that had flags and no verification was performed to resolve the flags: Date: 03/10/2021 Sequence #: 8550 Flag reported Date: 03/11/2021 Sequence #: 8580 Flag reported Date: 03/16/2021 Sequence #: 8637 Flag reported Date: 03/18/2021 Sequence #: 8702 Flag reported Date: 11/10/2021 Sequence #: 3003 Flag reported Date: 11/23/2021 Sequence #: 3256 Flag reported Date: 11/30/2021 Sequence #: 3363 Flag reported Date: 12/02/2021 Sequence #: 3437 Flag reported a. The laboratory failed to follow its own policy to invalidate analytes with flags according to the laboratory's own policy. 4. Review of the laboratory's submitted Form CMS-116 approved by the laboratory director on January 12, 2022 found the laboratory performs 23,400 hematology tests annually. 5.

	An interview with the laboratory director on January 12, 2022 at 11:30 hours in the break room after her review of the records confirmed the findings. Key: WBC - white blood cell CMS - Centers for Medicare and Medicaid Services
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 review of manufacturer instructions, patient records, and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of performing corrective action when patient test values were outside of the reportable range for four of four patient results from March 1, 2021 to July 31, 2021. The findings included: 1. Review of the manufacturer's instructions for the Medonic M Series hematology analyzer (Article no. 1504472, 02/2016) found the following under 11.3 Parameter Ranges: Linear Range: WBC: 0.2 -80.0 x 10^0/L RBC: 0.5 - 7.00 x 10^12/L PLT: 30 - 1800 x 10^0/L HGB: 2.0 - 23.0 g/dL 2. Review of patient test records from March 1, 2021 to July 31, 2021 found the following four of four patient test records that were reported outside of the analyzer's linear range. Date: 03-10-2021 Sequence #: 8872 Result: RBC = 8.69 (above linear range); HGB = 26.1 (above linear range) Date: 03-15-2021 Sequence #: 8618 Result: PLT = 6 (below linear range) Date: 03-18-2021 Sequence #: 8693 Result: PLT = 24 (below linear range) Date: 03-23-2021 Sequence #: 8764 Result: RBC = 8.62 (above linear range); HGB = 24.6 (above linear range) 3. Review of laboratory records found no documentation of the laboratory performing corrective action on the four of four patient results that were reported when the results were outside of the reportable range. 4. Interview of the laboratory director on January 12, 2022 at 11:30 hours in the break room confirmed the findings. Key: WBC - white blood cell RBC - red blood cell PLT - platelet HGB - hemoglobin dL - deciliter L - liter
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview of laboratory

	personnel, the laboratory director failed to ensure the laboratory retained environmental temperature records from January 1, 2020 to December 31, 2020. The findings included: 1. Review of laboratory records found no documentation of the laboratory retaining room temperature and humidity records of the laboratory from January 1, 2020 to December 31, 2020. 2. An interview with the laboratory director on January 12, 2022 at 11:30 hours in the conference room confirmed the findings. She stated the records could no be located at this time.