Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1071725	07/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas, Pllc	810 E Veterans Blvd Suite L, Palmview, 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.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Operator's guide for the Medonic M-Series hematology analyzer, the laboratory's calibration records for the Medonic M-Series hematology

	analyzer from 2017 to 2019, and staff interview, it was revealed the laboratory failed to have documentation of priming the instrument prior to calibration for 9 of 10 calibrations. Findings include: 1. A review of the Operator's guide for the Medonic M-Series hematology analyzer (Revision number 207053B RO6.24.15) states the following must be performed prior to calibrating the analyzer: - Run a normal whole blood or control to prime the instrument. 2. A review of the laboratory's calibration records for the Medonic M-Series hematology analyzer revealed the analyzer was calibrated on the following dates: 6/23/17 8/29/17 9/26/17 12/27/17 3/21/18 9/21/18 1 /25/19 3/20/19 6/19/19 7/10/19 3. A review of the calibration records for the above dates revealed 9 of 10 calibrations failed to have documentation of running a normal whole blood or control to prime the instrument. The only documentation of a normal whole blood run to prime the instrument was for the calibration done on 9/21/18. 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/31/19) on 7/31/19 at 10:35 in the laboratory, when asked to explain the steps for performing a calibration on the Medonic M-Series analyzer, the action of running a normal whole blood or control to prime the instrument was not mentioned. This confirmed the above 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 a review of the laboratory's policies, the laboratory's 'Room Temperature /Humidity Logs' from January 2018- March 2019, and staff interview, it was revealed the laboratory failed to perform corrective action when the laboratory's room temperature readings were outside of its acceptable range. Findings include: 1. A review of the laboratory's policy titled 'Storage and Temperature of Reagents and Supplies' states the following: "All reagent and supplies must be stored at the appropriate temperatures. For ambient temperature it is 18-25 degrees Centigrade." 2. A review of the laboratory's 'Room Temperature /Humidity Logs from January 2018- March 2019 revealed the following dates where the room temperature exceeded the allowable range of 64.4F- 77F or 18C- 25C: 1/22/18 64 5/8/18 60F 5/22/18 60 1/4/19 64 2/13/19 64F 3/7/19 64F 3/13/19 64F 3/25/19 64 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7 /31/19) on 7/31/19 at 10:55 in the laboratory, after review of the records, confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the

	laboratory's quality assessment program failed to identify and correct issues with analytic systems. Findings include: 1. A review of the Quality Assessment records from June 2017 - June 2019 revealed no documentation that the following issues were identified: 2. The laboratory failed have documentation of priming the instrument prior to calibration for 9 of 10 calibrations (refer to D5437). 3. The laboratory failed to perform corrective action when the laboratory's room temperature readings were outside of its acceptable range (refer to D5785).
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test results for June 2019, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for the notification of panic values. Findings include: 1. A review of the laboratory's policy titled 'Repeat and Panic Value Policy' states: "When a critical value is noted it will be verified by repeating the test and the result will be called or given to the Physician within 15-30 minutes. Document on the patient's report the date, time and provider receiving the panic value. This report will be scanned into the patient's medical record." Adult Critical Values for Hematocrit (HCT): Less Than 21% Greater Than 60% 2. A review of patient test records for June 2019 identified the following patient whose results met the laboratory's criteria as a 'panic value': Date ID Test 6/17/19 2.24.81 HCT=60.4 4. There was documentation of the notification of the provider as required by its policy. No documentation was provided. 5. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/31/19) on 7/31/19 at 11:30 in the laboratory, after review of the patient record, confirmed the above findings.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records for June 2019, and staff interview, it was revealed the laboratory director failed to ensure that patient results were reported only when the system was functioning properly. Findings

	include: 1. A review of the laboratory's policy titled 'Medonic M Series Parameters Codes and Flags' states the following: "The Medonic M Series has several parameters and system information messages related to the measured parameters and the instrument. These messages alert the operator of possible pathologic samples and parameter values and instrument errors." 2. Further review of the laboratory's policy titled 'Medonic M Series Parameters Codes and Flags' states the following: Indicator: OM Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. *Written next to this statement is: ->Action is refer specimen with these flags to reference lab for CBC or manual diff. 3. A review of patient test records from June 2019 identified the following patient results which were reported to the provider without resolution of flags to ensure the instrument was working properly: Date ID Flag(s) 6/19/19 4.10.15 OM 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7 /31/19) on 7/31/19 at 11:30 in the laboratory, when asked which results get reported out to the provider, was told, "The instrument printout is what we hand to the provider. It is the final result." This confirmed the above findings. Key: CBC= Complete blood count Diff= Differential