Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1071725	07/28/2021
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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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.
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 laboratory policies, patient test records, and confirmed in staff interview the laboratory director failed to ensure that patient results were reported only when the system was functioning properly for 1 of 5 patients reviewed in 2021 (July). Findings: 1. Review of the laboratory policy titled "Actions Protocol for WBC

	Differential FLAGS" stated: "Policy: The Medonic M Series Hematology Analyzer 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. The Operator's manual under section "WBC Differential abnormalities" recommends that action should be taken when the following indicators (flags) are revealed BD, NM, OM, and TM. The actions to be taken will be: If initial CBC was collected on an EDTA BD Tube, is well mixed and 15-20 minutes have lapsed and flags appear you may repeat the sample immediately once more to see if flags persist. If collected on a Safe T Fill tube and 15-20 minutes have not lapsed then you may have [sic] wait to repeat the sample. Note: EDTA Samples may take up to 15-20 minutes to reach equilibrium. Verify results by repeat testing on same sample which revealed the flags BD, NM, OM,,[sic] and TM. If flags persist then send an EDTA Tube that may be transported for testing at a Reference laboratory. Action: is to order a CBC and a possible manual Differential [sic] (if meeting criteria of reference lab) for confirmation of Physician's [sic] office lab results. Keep Log- Retain the CBC with flags that was obtained in physician's office and when results are received from Reference [sic] lab retain copy for Lab's [sic] records. Patient may be sent to get drawn and tested at a Reference [sic] lab with CBC results being sent back to Provider [sic]. Alternate Action: The Auto Diff section exhibiting the flags may be blocked off and not reported. The provider will make assessment of the patient without that portion of the report and only using the hemogram parameters." Further review of the laboratory's policy titled "Medonic M Series Parameters Codes and Flags" revealed the following: "Indicator BD Message WBC DIFF: High interference between populations. Description The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." ** Note next to the "action" statement was a handwritten statement that stated: "-> Action is Refer specimen with these flags to Reference Lab for CBC or manual Diff." 2. A review of patient test records for July 2021 identified the following patient results which were reported to the provider without resolution of flags to ensure the instrument was working properly: 07/28/2021 Patient ID: Seq 4178 Flag: BD The specimen was repeated, and the flag was unresolved. 3. During an interview on 07/28/2021 at 12:15 pm, Testing Person-1 (TP-1) stated that when patient CBC results have flags they are repeated. If the repeat continues to have flags she gives the provider both results and the provider makes the determination if they want to send the CBC to a reference lab for a manual differential. TP-1 was asked if the flags are blacked out from the pateint results and she stated "no". This confirmed the above findings.