Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0982501	08/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mycare Medical Of Texas Pllc	2121 E Griffin Parkway Suite 10, Mission, 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.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Based on direct observation, review of hematology quality control (QC) package insert and confirmed in interview, the laboratory failed to have a system in place to ensure QC was not utilized in excess of 20 times within 35 days according to the package insert. Findings: 1. During a tour of the laboratory on 08/02/2021 at 11:45 am, the surveyor observed the following control material stored in the refrigerator: 1

	Coulter 4C-ES Cell Control; high control lot #088200; manufacture expiration date: 10 /25/2021; labeled open date: 07/28/2021; initials (XX) 1 Coulter 4C-ES Cell Control; normal control lot #078200; manufacture expiration date: 10/25/2021; labeled open date: 07/28/2021; initials (XX) 1 Coulter 4C-ES Cell Control; low control lot #068200; manufacture expiration date: 10/25/2021; labeled open date: 07/28/2021; initials (XX) 2. Review of the package insert for the Coulter 4C-ES Cell Control stated "** Assumes that the Instruction Section of the package insert is performed a maximum of 20 times within 35 days." 3. During an interview on 08/02/2021 11:45 am, Testing Person (TP-1) was asked whether the laboratory had a mechanism in place to track the number of times control material was used (not to exceed 20 times within 35 days), she stated that she knew how many times the QC was analyzed and that she would change out the QC every 14 days. The number of times the control material was analyzed per lot number could not be assessed to ensure it was not utilized in excess of 20 times within 35 days.
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 laboratory policy, hematology and chemistry quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions for 1 of 26 runs in 2020 (December) and 7 of 78 runs in 2021 (May-July) for hematology controls and 7 of 26 runs in 2020 (December) and 24 of 77 runs in 2021 (May-July) for chemistry controls. Findings: 1. Review of the laboratory's policy "CONTROL POLICY" page 7.0 revealed: "For qualitative testing, two levels of control shall be run for every procedure on each day of use or for every eight hours of operation. Control materials should correlate with the specimen matrix. Controls will be evaluated daily against expected range for each lot number of controls. Control results shall be recorded and if controls are beyond the expected range then remedial actions must also be recorded. All control results and remedial actions must be recorded and records kept for at least two years. Patient testing must not be performed or reported when control test results are outside the expected range. Use the following forms to record controls and remedial actions (QC Out-Of-Limits Log Sheet) when controls are outside the expected range. Additionally, use the "Daily Control Sample Troubleshooting Checklist", found in this section, to help you resolve daily control problems. All control records and Remedial Action Sheets will be reviewed, signed /initialed, and dated monthly by the Laboratory Technical Consultant." Page 7.001 of the policy revealed the following: "IT IS THE POLICY OF THIS LABORATORY TO DO THE FOLLOWING WHEN CONTROLS ARE NOT WITHIN RANGE: 1. ENSURE THAT CONTROLS ARE NOT EXPIRED THEN REMIX AND RERUN CONTROL SAMPLE; IF CONTROLS FAIL THEN, 2. OPEN A NEW VIAL OF CONTROLS AND RUN; IF CONTROLS FAIL THEN, 3. VERIFY THAT

CONTROL RANGES ARE CORRECT AND THAT THE CORRECT LEVEL OF CONTROL IS EVALUATED- THEN, 4. ENSURE THAT ALL SPECIMENS AND REAGENTS ARE AT THE RIGHT TEMPERATURE, THEN, 5. EVALUATE MAINTENANCE SCHEDULE, ENSURE THAT ALL OF MANUFACTURERS RECOMMNEDATIONS ARE FOLLOWED AND THAT MAINTENANCE PROCEDURES LIKE BLEACHING OR CLEANING OF THE APERATURES ARE BEING DONE AS REQUIRED. 6. EVALUATE CALIBRATION; IF NECESSARY, RECALIBRATE UNIT AND RUN CONTROLS; IF CONTROLS FAIL THEN, 7. CALL TECHNICAL SUPPORT FOR HELP. 8. ENSURE THAT ALL REMEDIAL ACTION STEPS ARE DOCUMENTED. MOST IMPORTANTLY, ENSURE THAT NO PATIENTS ARE REPORTED UNTIL THE PROBLEM HAS BEEN CLEARED AND CONTROLS ARE IN RANGE." 2. Review of Beckman Coulter ACT Diff 2 QC records revealed the laboratory failed to document corrective actions for QC failures in 2020 and 2021 on the following dates and times: QC normal level control lot #78900; expiration date: 02/15/2021 12/23 /2020 Normal control 10:30 am QC failed for PLT 11:30 am QC was repeated and passed QC normal level control lot #77500; expiration date: 07/23/2021 QC high level control lot #87500; expiration date: 07/23/2021 05/14/2021 High control 9:26 am QC failed for RBC, HCT, HGB, WBC 9:44 am QC was repeated and passed 05/20/2021 Normal control 09:26 am QC failed for WBC 09:29 am QC was repeated and passed 06/29/2021 High control 8:39 am QC failed for PLT 9:15 am QC was repeated passed 06/30/2021 Normal control 9:11 am QC failed for RBC 9:30 am QC was repeated and passed 07/15/2021 High control 9:30 am QC failed for RBC, HCT, HGB, WBC 9:34 am QC was repeated and passed QC low level control lot #68200; expiration date: 10 /25/2021 QC normal level control lot #78200; expiration date: 10/25/2021 QC high level control lot #88200; expiration date: 10/25/2021 07/26/2021 Low control 4:02 pm QC failed for GRAN% 4:05 pm QC was repeated and passed 07/28/2021 Normal control 8:11 am QC failed for HGB 8:16 am QC was repeated and passed High control 8:16 am QC failed for HGB, MCHC 8:18 am QC was repeated and passed 8: 43 am QC was repeated and failed for HGB, MCHC, MCH 1:05 pm QC was repeated and passed The laboratory failed to document corrective action for the above QC failures. 3. Review of Roche Integra 400 plus QC records revealed the laboratory failed to document corrective actions for QC failures in 2020 and 2021 on the following dates and times: QC level 1 control lot #423926; expiration date: 02/28 /2022 QC level 2 control lot #423932; expiration date: 02/28/2022 12/03/2020 Level 2 control 11:55 am QC failed for Potassium 12:10 pm QC was repeated and passed 12 /04/2020 Level 2 control 10:29 am QC failed for Calcium 11:10 am QC was repeated and passed 12/09/2020 Level 1 control 9:33 am QC was run in duplicate one run failed for Potassium and the other run passed 10:10 am QC was repeated and passed 12/12/2020 Level 1 control 10:15 am QC failed for Potassium 10:26 am QC was repeated and passed 12/16/2020 Level 2 control 8:28 am QC failed for Potassium 9:40 am QC was repeated and passed 12/30/2020 Level 1 control 9:30 am QC failed for Potassium 10:20 am QC was repeated and passed 12/31/2020 Level 2 control 9:30 am QC failed for Potassium 10:20 am QC was repeated and passed 05/07/2021 Level 2 control 10:24 am QC failed for TBIL, Albumin, Alk Phos, BUN 11:36 am QC was repeated and passed 05/17/2021 Level 2 control 9:28 am QC failed for TBIL, Albumin, Alk Phos, AST 9:58 am QC was repeated and passed 06/01/2021 Level 1 control 9:20 am QC failed for BUN 9:45 am QC was repeated and passed 06/02/2021 Level 1 control 10:39 am QC failed for BUN, Alk Phos 11:56 am QC was repeated and passed Level 2 control 10:40 am QC failed for Chol 11:56 am QC was repeated and passed 06/05/2021 Level 2 control 1:45 pm QC failed for Albumin 2:27 pm QC was repeated and passed 06/07/2021 Level 2 control 9:05 am QC failed for Chol 9:31 am QC was repeated and passed 06/08/2021 Level 1 control 8:45 am QC failed for

	Alk Phos 9:36 am QC was repeated and passed Level 2 control 9:03 am QC failed for Alk Phos 9:36 am QC was repeated and passed 06/09/2021 Level 1 control 8:19 am QC failed for Alk Phos 8:46 am QC was repeated and passed Level 2 control 8:19 am QC failed for Calcium 8:46 am QC was repeated and passed 06/10/2021 Level 1 control 9:00 am QC failed for Albumin 2:38 pm QC was repeated and passed Level 2 control 9:00 am QC failed for Calcium 2:38 pm QC was repeated and passed 06/11 /2021 Level 1 control 8:08 am QC failed for Albumin 9:17 am QC was repeated and failed 9:28 am QC was repeated and passed Level 2 control 8:08 am QC failed for Albumin 9:17 am QC was repeated and failed 10:54 am QC was repeated and passed 06/14/2021 Level 1 control 9:09 am QC failed for Alk Phos 9:31 am QC was repeated and passed Level 2 control 9:09 am QC failed for Alk Phos 9:31 am QC was repeated and passed 06/15/2021 Level 1 control 9:01 am QC failed for Alk Phos, Albumin 11: 02 am QC was repeated for Alk Phos and passed 11:16 am QC was repeated for Albumin and passed Level 2 control 9:34 am QC failed for Alk Phos, Albumin 11:02 am QC was repeated for Alk Phos and passed 11:17 am QC was repeated for Albumin and passed 06/19/2021 Level 1 control 12:49 pm QC failed for Albumin 1:20 pm QC was repeated and passed Level 2 control 1:06 pm QC failed for Albumin 1:29 pm QC was repeated and passed 06/21/2021 Level 1 control 10:06 am QC failed for Albumin 10:34 am QC was repeated and passed Level 2 control 1:06 pm QC failed for Albumin 1:29 pm QC was repeated and passed 06/23/2021 Level 2 control 9:44 am QC failed for Chol, BUN 10:07 am QC was repeated and passed 06/24/2021 Level 1 control 9:36 am QC failed for BUN 10:21 am QC was repeated and passed Level 2 control 9:36 am QC failed for BUN 10:20 am QC was repeated and passed 06/25 /2021 Level 1 control 9:07 am QC failed for Alk Phos 10:01 am QC was repeated and passed 06/26/2021 Level 1 control 9:06 am QC failed for Alk Phos 9:28 am QC was repeated and passed 07/08/2021 Level 1 control 9:37 am QC failed for BUN 10:02 am QC was repeated and passed 07/29/2021 Level 1 control 9:32 am QC failed for BUN 9:38 am QC was repeated and passed Level 2 control 9:32 am QC failed for BUN 9: 38 am QC was repeated and passed Ammonia/Carbon dioxide (AMM/CO2) control level 1 control lot# 500126; expiration date 10/31/2021 Ammonia/Carbon dioxide (AMM/CO2) control level 2 control lot# 500127; expiration date 10/31/2021 07/13 /2021 AMM/CO2 level 1 control 10:49 am QC failed for CO2 11:11 am QC was repeated and passed AMM/CO2 level 2 control 10:49 am QC failed for CO2 11:11 am QC was repeated and passed 07/21/2021 AMM/CO2 level 1 control 11:03 am QC failed for CO2 11:06 am QC was repeated and passed AMM/CO2 level 2 control 11: 03 am QC failed for CO2 11:06 am QC was repeated and passed 07/23/2021 AMM /CO2 level 1 control 10:18 am QC failed for CO2 10:39 am QC was repeated and passed 07/28/2021 AMM/CO2 level 1 control 9:10 am QC failed for CO2 10:18 am QC was repeated and passed The laboratory failed to document corrective action for the above QC failures. 4. During an interview on 08/02/2021 at 10:30 am, Testing Person-1 stated that she did not document corrective actions for QC failures and that she just repeated the QC when it failed, this confirmed the above findings. Word Key: RBC - red blood cell HCT - hematocrit HGB - hemoglobin PLT - platelet WBC - white blood cell MCH - mean corpuscular hemoglobin GRAN% - granulocyte percent MCHC - mean corpuscular hemoglobin concentration TBIL- total bilirubin ALk Phos- Alkaline Phosphatase BUN - blood urea nitrogen AST - aspartate aminotransferase Chol - cholesterol