Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0982501	09/24/2019
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	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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to have a mechanism in place to ensure that specimens received in the laboratory with same name or date of birth could be distinguished. The findings were: 1. Direct observation by the surveyor on 09/24/2019 at 09:03 hours in the laboratory refrigerator revealed one sample was not labeled with unique identifiers. 2. Review of the laboratory's policy "Specimen Identification"

	approved by the laboratory director on 09-17-07 stated, "Each specimen must have unique patient identifiers such as patient name, birth date, social security number, or other identifying number. The identifiers should be used throughout the testing process, so results can be confidently used in patient care. This can be done by placing an identification label on each specimen when it is collected and by labeling all related materials (test tubes, slides etc.) with the same identification information." 3. On 09-24-2019 at 09:03 hours in the laboratory, when asked what was in the unlabeled container, TP #1 (as listed on CMS-Form 209) confirmed that the specimens should have had unique identifier labels placed on it. KEY TP #1- Testing personnel #! CMS - Centers for Medicare and Medicaid Services
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient records, and confirmed in interview of facility personnel, the laboratory failed to ensure normal ranges on patient final reports were accurate. The findings were: 1. Review of the laboratory's policy titled, "Urine Sediment Examination Procedure" approved by the laboratory director with no approval date under, "Reporting Results: Norrmal Ranges" it stated: "WBC 0-3 hpf" "RBC 0-3 hpf" 2. Review of 2 patient final reports revealed the reference range for Urine WBC and Urine RBC was 0-5/hpf. 3. The laboratory failed to ensure patient normal ranges matched the laboratory's laboratory policy. 4. An interview with the technical consultant on September 24, 2019 at 14:30 hours confirmed the findings. Key: WBC - white blood cell RBC - red blood cell hpf - high power field