Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0971834	(X3) Date Survey Completed 03/09/2022
Name of Provider or Supplier Tcr Medical Corporation	**Street Address, City, State** 9025 Balboa Ave Ste 105, San Diego, CA	

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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance/Assessment (QA) records of the patient test result reports, and interview with the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess in the postanalytical systems, and failed to verify and to ensure the accuracy, reliability, and timely of the patient test result reports, and failed to assure the consistency of the patient demographic information among the patient test result reports, biopsy slides and the offical documents inside of the patient chart files. The findings included: a. The laboratory performed skin biopsy histopathology. b. The laboratory failed to follow written policies and procedures to verify and to ensure the accuracy, reliability, timely of the patient test result reports. c. Randomly review of 6 patient test result reports to verify the accuracy, reliability, and timely of the patient test result reports. d. One out of the 6 randomly pulled patient test result reports, identified with a specimen collection date of January 24, 2020, Specimen Number TCR20-00004, and site of biopsy, left medial ankle. e. Copies of the following sheets: "Patient Demographics", "United HealthCare" "Medicare Health Insurance" cards", "Patient Categories and Study Tracking" and the "Pathology Report" were reviewed. f. The patient's first name was identified as "Lawrence" in the Pathology Report and the biopsy slide labeling. g. While "Larry" the first name was noted in the "United HealthCare" and :Medicare Health Insurance" cards, as well as "Patient Categories and Study Tracking" sheet. h. On the "Patient Categories and Study Tracking" forms, "Larry" was crossed out and "Lawrence" was written without an initial and/or when/date to account for the correction. i. The laboratory personnel at

	the time of survey (3/9/2022 @ 12:55 PM) cannot provide reasonable explanations for the inconsistency of the patient's demographic information in the test result report.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance/Assessment (QA) records of the patient test result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to ensure the accuracy, reliability and timely of the patient test result reports and to assure the consistency of the test final reports with patient demographic information as provided by the patient and its legal documents. The findings included: a. The laboratory performed skin biopsy histopathology. b. The laboratory director failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided, see D-5891.