Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0679177	09/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Howard Milstein Md, A Medical Corp	7334 Girard Ave Ste 201, La Jolla, 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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyors' interviews with the laboratory's office manager (OM) and record review of pre-analytic, analytic, and postanalytic remedial action records on September 2, 2022; the laboratory failed to establish written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory's systems. Findings included: 1. According to laboratory's OM, during preanalytic, analytic, and postanalytic review of patients' processed Mohs slides, if a patient specimen was received or a report was issued that did not meet the laboratory's criteria for acceptability, a description as to why the specimen or report did not meet the laboratory's criteria for acceptability would be documented, appropriate corrective actions would be taken and noted, and the incident would be captured for quality assessment review. 2. Based on surveyor review of policies and procedures on 9/2/2022 at approximately 1:00 p.m.; it was determined that the laboratory failed to maintain written policies and procedures detailing the quality assessment process described. 3. According to the LD declaration statement, the laboratory performed approximately 42 patient tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the office manager (OM); it was determined that the laboratory failed to update protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey September 2, 2022, at approximately 11:45 a.m. the procedure manual in place did not reflect the current practice and had not been recently reviewed, approved, signed, and dated by the laboratory director of such changes. 2. The OM affirmed on September 2, 2022, that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 42 patients test annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyors' observation, examination of laboratory reagents, and interview with the office manager (OM); it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, September 2, 2022, at approximately 11:30 a.m. the surveyor found the KOH reagent used for microscopic examination for the presence of yeast and fungal elements lot number 3106813, not labelled, and used beyond its expiration date (3/8/2012). 2. The OM affirmed on 9/2/2022 at approximately 11:35 a.m. testing personnel using the KOH reagent beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 4 KOH mycology samples annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory's procedure manual, lack of documentation, and interview with the laboratory's office manager (OM), it was determined that the laboratory failed to perform and document maintenance and calibration of the microscopes as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's standard operating procedure (SOP) indicates that annual maintenance and calibration by a contracted equipment service according to manufacturer's requirements be performed on one Nikon microscope used in the laboratory. 2. The OM confirmed on 09/02/2022 at approximately 11:15 a.m. that the laboratory failed to follow SOP for

	maintenance and calibration of the microscope for the years 2021 and 2022. 3. According to the annual test volume declared by the laboratory on 09/1/2022; the laboratory performs approximately 46 tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's records for policies and procedures, lack of calibration records for the microscope, use of expired reagents in Mycology, lack of a Quality Assessment plan, and interview with the laboratory director and office manager on September 2, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D5391, D5429, D5407, and D5417.