Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2146684	07/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Michelle Aszterbaum, Md Inc	360 San Miguel Ste 406, Newport Beach, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P), review of the "Verification of Test Accuracy" (ETA) for histopathology testing records, and interview with the laboratory personnel, it was determined that the laboratory failed to ensure, at least twice annually, and verify the accuracy of histopathology the laboratory performed that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory performed skin biopsy and Mohs surgery procedures including examination of the skin histopathological slides. b. The histopathology testing system is not included in the CLIA subpart I of 42 CFR part 493. c. To ensure the accuracy of the testing results, the laboratory elected to perform EPA by sending out histopathological slides to qualified personnel for peer review at least twice annually. d. The laboratory failed to perform ETA in 2019 and 2020 to verify the accuracy of the testing results. e. The laboratory performed histopathology testing in approximately 80 patient cases monthly. f. The laboratory personnel affirmed (7/20/21 @ noon) that the laboratory failed to perform ETA twice a year to ensure and verify the accuracy of the testing results.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P), review of "Verification of Test Accuracy" (ETA) for histopathology testing records, and interview with the laboratory personnel, it was determined that the laboratory failed to follow written P&P for an ongoing mechanism to evaluate, monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. The laboratory performed skin biopsy and Mohs surgery procedures including examination of the skin histopathological slides. b. The histopathology testing system is not included in the CLIA subpart I of 42 CFR part 493. c. To ensure the accuracy of the testing results, the laboratory elected to perform ETA by sending out histopathological slides to a qualified personnel for peer review at least twice annually. d. The laboratory written P&P states in item V. 1. The policy of Michelle Aszterbaum MD., Inc. is to send a minimum of 1 case, twice a year for peer review by a CLIA certified laboratory. In compliance with CLIA requirements for proficiency testing of our laboratory director. e. The laboratory, in 2021, sent out total of six (6) tissue slides, 2 from 2019, 2 from 2020 and 2 from 2021 to a qualified peer to examine and received "Agree with Dx" for all six (6) cases sent. The qualified peer had signed the initial and dated them all on the same date of 7/6/21. f. The laboratory failed to follow its P&P (see d. above), instead sent out 6 cases from three years (2019 thru 2021) for peer review in one time.
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 policies and procedures (P&P), review of the "Verification of Test Accuracy" (ETA) for histopathology testing records, and interview with the laboratory personnel, 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 identify failures in quality as they occur. The findings included: a. The laboratory performed skin biopsy and Mohs surgery procedures including examination of the skin histopathological slides. b. To ensure the accuracy of the testing results, the laboratory elected to perform ETA by sending out histopathological slides to qualified personnel for peer review at least twice annually. c. The laboratory failed to perform ETA in 2019 and 2020 to ensure and verify the accuracy of the testing results see D-5217 d. The laboratory failed to follow written P&P to send out the tissue slides with a minimum one (1) case twice in a year for peer review, see D-5791.