Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2166466	12/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Premier Dermatology And	168 N Brent St, Ste 403b, Ventura, 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 the lack of the laboratory's policies & procedures, review of five (5) random patients Mohs reports, quality control records, proficiency testing records, and interview with the laboratory staff on December 23 2020 at 12:45 p.m.; it was determined that the laboratory failed to verify, at least twice annually, the accuracy of its Mohs test for the year 2020. The findings included: 1. The laboratory did not have any documentation showing that it had verified its Mohs test accuracy for the year 2020. Therefore, the accuracy of the laboratory's test results to the patients for Mohs procedure, cannot be assured. 2. The laboratory staff affirmed on 12/23/2020 at approximately 1:45 p.m., that the laboratory did not have any record to verify its Mohs test accuracy for the year 2020. 3. The laboratory's testing declaration form signed by the laboratory director, stated that the laboratory performs 250 Histopathology Mohs tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by:

	Based on the lack of laboratory written policies and procedures and interview with the laboratory personnel, it was determined that the laboratory failed to have available and follow written procedures for Histopathology (Mohs testing) test procedures performed in the laboratory. The findings included: 1. On the day of the survey on December 23, 2020 at approximately 1:00 p.m. the laboratory failed to provide written policies and procedures for Histopathology test procedures performed in the laboratory. 2. For five (5) out of five (5) random patient test results reviewed covering period from 01/14/2020 to 10/27/2020 all the patients had Mohs test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The laboratory staff confirmed on 12/23/2003 at approximately 2:30 p.m. that the laboratory did not have written policies and procedures available for the Mohs test performed in the laboratory.
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 interview with the laboratory staff on December 23, 2020 and review of laboratory records; it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the pre-analytic, analytic, and post-analytic phases of clinical testing. The findings included: 1. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in all phases of testing for the Mohs procedure prior to reporting patient test results. 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified with the failure in establishing the procedure manual for Mohs testing from pre-analytic, analytic, and post-analytic phases of clinical testing (See D5401). 3. The laboratory staff confirmed on 12/23/2003 at approximately 2:00 p.m. that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in all phases testing of the Mohs procedure. 4. Based on the declaration of test volumes for the year 2020 submitted on 12/23/2020; the laboratory processed and reported 250 Histopathology samples for the Mohs test procedure.
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 the lack of established policies and procedures (D5401), failure to establish

	a Quality Assurance program for Mohs testing from pre-analytic, analytic, and post-analytic phases of clinical testing (D5791), and lack of verification at least twice annually the accuracy of the Mohs procedure for the year 2020 (D5217); it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the Mohs 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.