Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1045230	02/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Thousand Oaks Dermatology	415 E Rolling Oaks Dr Ste 110, Thousand Oaks, 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
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient testing log, and interview with the staff on February 13, 2023, at 2:25 pm, the laboratory failed to have a system in place to ensure patient-specific data are reliably sent from the point of data entry to final report destination, in a timely manner. The findings include: 1. The laboratory biopsied 9 patients on 1/10/2023, however the results were still pending on February 13, 2023. The laboratory's average turnaround time is 2 days, however, the laboratory failed to report the results in a timely manner and may have impacted patient care. 2. The laboratory staff on February 13, 2023, at 2:25 pm, affirmed that the laboratory did not report the test results on a timely manner. 3. The laboratory's testing declaration form, signed by the laboratory director's designee on 1/12/2023, stated that the laboratory performs approximately 1,300 tests, annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient test results, and interview with the staff on February 13, 2023, at 2:15 pm, the laboratory failed to have the correct date on the test report. The findings include: 1. The laboratory read biopsy slides later than the date listed on all reports. The laboratory staff informed that the test report date is always 2 days later of biopsy regardless of the reading date. The date of the test report is the date results were generated as a final report. 2. The laboratory staff on February 13, 2023, at 2:15 pm, affirmed that the laboratory did not put the correct date on the test report. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/6/2023, stated that the laboratory performs approximately 1,300 tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient test results, and interview with the staff on February 13, 2023, at 2:15 pm, it was determined that the laboratory director failed to direct the overall operation and administration of the laboratory. The findings include: See D5801 and D5805.
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 Surveyor review of laboratory's patient test results, and interview with the staff on February 13, 2023, at 2:15 pm, it was determined that the laboratory director

	failed to ensure the quality of the laboratory services provided. The findings include: See D5801 and D5805.