Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2142114	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oak Dermatology	550 E Devon Ave - Ste 200, Itasca, IL	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview; safety procedures were not established and observed to ensure protection from physical, chemical, biochemical and electrical hazards, and biohazardous materials. Findings: 1. On 05/10/18, during the walk-through of the laboratory, the surveyor observed that there was a microtome; a cabinet with staining solutions and patients' stained slides; 2 massage chairs; a desktop fountain; and a refrigerator with bottled drinking water. The Mohs technician explained that the 2 massage chairs; desktop fountain; and refrigerator belonged to the dermatology office that they shared space with. The surveyor noted that the other dermatology office had its own CLIA Certificate. However, there was no separation of the 2 spaces. 2. During survey date 05/10/18, the Mohs Technician confirmed the surveyor's findings.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by:

	Based on review and interview; the laboratory failed to establish and follow written policies and procedures that ensured positive identification and optimum integrity of the patients' specimens form the time of collection of the specimen through completion of testing and reporting of results. Findings: 1. Review of the laboratory's procedures manual revealed that patients' specimens are submitted with a Mohs map that includes the following information: a. Patient's first and last name b. Medical Record # c. Date of Birth e. Tissue Site f. Case Number (a different Case number for each Tissue Site) e. Date g. Diagnosis h. Referring Physician 2. Review of patient testing log revealed that the following information is documented: a. Patient's first and last name b. Medical Record # c. Date of Birth d. Tissue Site e. Case Number f. Number of Stages g. Date 3. Reviews of 4 patient's slides revealed that there was no tissue site recorded on the labels of 4 of 4 patients' slides. 4. During survey date 05/10 /18, the Mohs technician confirmed the surveyor's findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, review and interview; the procedure manual did not include the following: *The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. *Description of the course of action to take if a test system becomes inoperable. Findings: 1. During survey date 05/10/18, the surveyor observed that the laboratory had 2 system they used to report patients' test results. One is a paper report that was entered into letter format and printed. The other is an electronic reporting system. 2. Review of the laboratory's procedures manual revealed that there were no procedures that described the laboratory's process for recording and/or documenting patients' test results. 3. During survey date 05/10/18, the Mohs technician confirmed the surveyor's findings.
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 review and interview, test reports did not include the following: *Specimen source, when appropriate. Findings: 1. The laboratory's procedures manual indicates that each patient's specimen will get a separate case # per specimen site. 2. Review of 4 patients' test reports revealed that the specimen source (Case #) was not included in the reports of 4 of 4 reports reviewed. 3. During survey date 05/10/18, the Mohs technician confirmed the surveyor's findings.