Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2142114	09/18/2019
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**
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; CLIA survey forms; accession logs; and patient test records, and interviews with the histology technician and laboratory director, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory system requirements as specified. Findings: 1. Review of the laboratory's Quality assessment policy (bullet #2) states, "All Quality Control (QC) records (such as log sheets, logs of test requisitions, test report and Receipt/QA or regents and culture media) will be reviewed by the Laboratory Director or an appropriate, designated staff member. All forms will be signed and dated on the date of review." 2. The laboratory's procedures manual revealed that the laboratory director assigned himself as Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel of Histopathology testing. 3. Review of CLIA survey FORM CMS 209 (Laboratory Personnel Report) show that the laboratory director was listed as Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel for High Complexity Histopathology testing. 4. On survey date 09/18/19 at 11:30 AM, the surveyor selected 6 patients from the Mohs Accession log. The Mohs Accession Log included the following information: a. Mohs# b. Patients' Last and First Names c. Specimen Site d. Type of Cancer e. Stage 5. The surveyor requested the following information for the 6 patients selected: a. Mohs Map b. Quality Control (QC)Records c. Patients' slides d. QC slides 6. Mohs maps were used as the official surgery report where the following

	information was documented: a. Date of Service (DOS) b. Patient's Last and First names c. Mohs# d. Specimen site d. Tissue Orientation 7. One of 6 patient's specimen sites documented on the Mohs Surgery Report / Map did not match information that was recorded on the Mohs Accession Log. The site documented on the Mohs Surgery Report / Map was recorded as R Mid Paraspinal, while "Left Mid Paraspinal" was recorded on the Mohs Accession Log. The same Mohs # was recorded for both. 8. There was no documentation to show any corrective actions to correct the error or if that the laboratory director performed Quality Assessment reviews from May 2018 through September 18, 2019. 9. On 09/18/19 at 12:00 PM, the laboratory director confirmed the surveyor's findings.