Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0871989	02/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Skin Surgery	10100 West 191st Street, Mokena, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to retain pathology slides for 5 of 5 patients who had frozen tissue pathology performed. Findings Include: 1. Review of patient testing found for 5 of 5 patient test results reviewed the laboratory failed to have the corresponding stained slides for review on the date of survey 2-26-2019. Patient Identification Testing Date P1 01-30-2019 P2 12-19-2018 P3 11-28-2018 P4 08-29-2018 P5 07-25-2018 2. On survey date 02-26-2019, at 1:00 pm, the TS confirmed the laboratory did not have the stained slides on-site for review.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to document pathology quality control records for differential staining for 5 of 5 patient testing dates reviewed. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Frozen Section IOC Protocol and Safety", which failed to indicate how quality control differential staining is performed and documented with Toluidine Blue each day of patient testing. 2. Review of patient testing result for frozen tissue pathology found for 5 of 5 testing dates (1-30-19, 12-19-18, 11-28-18, 8-29-18, and 7-25-18) the "KWIK-DIFF Stain and Miscellaneous Change Log" failed to document quality control records for differential staining with Toluidine Blue. 3. On survey date 02-26-2019, at 1:00 pm, the TS confirmed quality control records were not documented for differential staining when frozen tissue histopathology testing was performed.
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 of laboratory records and interview with the technical supervisor (TS); the laboratory test reports failed to indicate the name and address where frozen tissue pathology was performed for 5 of 5 patient test reports reviewed. Findings Include: 1. Review of patient test reports found for 5 of 5 patient test reports reviewed the reports failed to indicate the name and address where frozen tissue pathology was performed. Patient Identification Testing Date P1 01-30-2019 P2 12-19-2018 P3 11-28-2018 P4 08-29-2018 P5 07-25-2018 2. On survey date 02-26-2019, at 1:00 pm, the TS confirmed the name and address of the laboratory where frozen tissue pathology was performed was not documented on the patient test reports.
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 surveyor review of laboratory records and interview with the technical supervisor (TS); the laboratory director failed to establish a quality assessment program. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Frozen Section-Quality Assurance and PT". The policy failed to indicate quality assessment monitoring for this specific CLIA laboratory and

	references quality assessment at an alternate CLIA laboratory. Additionally, the proficiency testing portion only refers to proficiency testing performed under an alternate CLIA number and not specific to frozen tissue pathology performed under this CLIA number. 2. On survey date 2-26-2019, at 1:00 pm, the findings were confirmed by the TS.