Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0677176	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Illinois Dermatology Institute Llc	11824 Southwest Highway - Ste 210, Palos Heights, 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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory office manager (OM); the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform and document bi-annual method accuracy assessments for Mohs histopathology testing in 2017 through 2019. See D5217.
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 review of laboratory records and interview with the office manager (OM); the laboratory failed to perform bi-annual method accuracy evaluations for histopathology testing in 2017 through the date of survey in 2019. Findings Include: 1. Review of PT records found no method accuracy assessments for Mohs histopathology testing in 2017, 2018, and 2019. 2. Based on review of laboratory testing 163 Mohs histopathology procedures were performed in 2017 through the date of survey (5-15-19) in 2019. 3. Interview with the OM, on 5-15-2019, at 1:45 pm,

	confirmed the laboratory failed to perform the bi-annual method accuracy evaluations for Mohs histopathology testing in 2017 through date of survey (5-15-19) in 2019.
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 review of laboratory records and interview with the office manager (OM); the laboratory failed to have a reliable system to ensure that test results are accurately transferred to the final report destination for potassium hydroxide (KOH) preparations. Findings include: 1. Review of patient test records for KOH preparations found 2 of 10 test results reviewed failed to be transcribed correctly to the final report destination (the patient chart) from the results documented on the "KOH/Scabie log." a. Patient ID: P10 tested on 09-27-2018 - Result not transcribed to the patient chart. b. Patient ID: P15 tested on 09-14-2018 - Result documented in the "KOH/Scabie log" as KOH positive but documented in patient chart as positive for scabies. 2. On survey date 05-15-2019, at 1:45 pm the above findings were confirmed by the OM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with the office manager (OM); the technical consultant (TC) failed to ensure annual competency assessments were completed for all testing personnel performing mycology testing in 2018. Findings Include: 1. Review of competency records for 9 of 9 testing personnel, as listed on the CMS-209, found no documented competency assessments in 2018 for potassium hydroxide (KOH) examinations. 2. Review of the laboratory's policy and procedure manual identified the policy, "Competency Assessment Policy", which stated: "Competency testing will be done annually by current providers and bi annually by new providers." 3. On survey date 05-15-2019, at 1:45 pm, the OM confirmed that annual competency assessments were not completed in 2018 for KOH examinations. B. Based on review of laboratory records and interview with the office manager (OM); the technical consultant (TC) failed to ensure annual competency assessments were completed for 8 of 9 testing personnel performing parasitology testing. Findings Include: 1. Review of competency records for 8 of 9 testing personnel (TP), as listed on the CMS-209, found no documented competency assessments in 2018 for scabies wet prep examinations. 2. Review of the laboratory's

	policy and procedure manual identified the policy, "Competency Assessment Policy", which stated: "Competency testing will be done annually by current providers and bi annually by new providers." 3. On survey date 05-15-2019, at 1:45 pm, the OM confirmed that annual competency assessments were not completed in 2018 for 8 of 9 TP for scabies wet prep examinations.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interviews with the office manager (OM); the laboratory failed to employ testing personnel (TP) who met the qualification requirements of 493.1423. Findings Include: 1. The laboratory failed to have educational documentation for TP#9, as listed on the CMS-209. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with the office manager (OM); the laboratory failed to have qualifying documents for all moderate complexity testing personnel (TP) listed on the CMS-209. Findings Include: 1. No education documents were available to review for TP#9. 2. On survey date 5-15-2019, at 1:45 pm, the surveyor findings were confirmed by the OM.
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 review of laboratory records and interview with the office manager (OM);

	the laboratory director (LD) failed to ensure the quality assessment program was maintained to assure the quality of laboratory services provided. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the documents, "Quarterly Quality Assurance Record" and "2017 Quarterly Review" forms, used to monitor quality of the laboratory testing. 2. Review of these documents found no quarterly reviews were completed in 2017 through the date of survey (5-15-19) in 2019. 3. On survey date 05-15-2019, at 1:45 pm, the OM confirmed the quality assessment program had not been maintained and ongoing problems were not assessed or resolved.