Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2054063	08/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Mohs Surgery Institute	303 N Hershey Rd, Bloomington, 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, lack of documentation, patient test records and interview with testing personnel (TP) #2; the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299 for histopathology testing. Findings include: 1. The laboratory failed to perform bi-annual method accuracy evaluations for histopathology testing in 2018 through 2021. See D5217. 2. The laboratory failed to identify and perform corrective actions for diagnosis discrepancies identified for the first mohs biannual method accuracy evaluation for 2020. See D5221. 3. The laboratory failed to check and document quality control (QC) reviews for immunohistochemical, special and differential staining from 2-11-2021 through the date of survey (8-19-2021) by qualified laboratory personnel. See D5601.
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, lack of documentation and interview with testing personnel (TP) #2; the laboratory failed to perform bi-annual method accuracy

	evaluations for histopathology testing in 2018, 2019 and 2021. Findings Include: 1. Review of proficiency testing (PT) records found the laboratory procedure, "Proficiency Testing", which outlined the PT policy for histopathology testing performed by the laboratory. The policy indicated the following: a. "Biannually, the Lab Supervisor or CLIA compliance officer will send three cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Pathologist or Dermatologist" b. "Biannually, the Lab Supervisor or CLIA compliance officer will send three cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Pathologist or Dermatologist. The evaluator will provide a score for adequate preparation. 2. Further review of PT records found the laboratory failed to have documented biannual method accuracy evaluations as outlined in the laboratory's PT policy for the years 2018 through 2021 for histopathology testing. 3. Interview with TP#2 on 8-19-2021, at 3:00 pm, confirmed the laboratory failed to perform the bi-annual method accuracy evaluations for histopathology testing in 2018 through 2021.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test records, lack of documentation and interviews with testing personnel (TP) #2; the laboratory failed to identify unsatisfactory performance for the first mohs histopathology biannual method accuracy evaluation of 2020 and document the corrective action taken. Findings Include: 1. Review of biannual method accuracy proficiency testing (PT) records for mohs histopathology testing identified the PT record for the first biannual method accuracy evaluation of 2020. 2. Review of the first method accuracy evaluation of 2020 for mohs histopathology testing found the second pathologist that reviewed the three selected cases indicated that case #2 was positive for tumor at stage I and no stage II slides were provided. 3. Review of the patient test record for case #2, identified as P9, indicated the following "A total of 1 stage was required to clear the tumor". 4. Review of proficiency testing records found no corrective action was documented for the discrepancy identified for case #2/P9. 5. On survey date 8-19-2021 at 3:00 pm, TP#2 confirmed the laboratory failed to identify and document a corrective action for the first mohs histopathology method accuracy evaluation of 2020.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with testing personnel (TP) #2; the laboratory failed to document the discontinuance of all laboratory procedures for parasitology testing. Findings Include: 1. Review of the laboratory procedure manual identified the procedure, "Ectoparasites". 2. Interview with TP#2 at

	9:15 am, on 8-19-21, stated the laboratory had discontinued ectoparasites/scabies wet prep testing. 3. On survey date 8-19-2021, at 3:00 pm, TP#2 confirmed that ectoparasite testing was no longer performed but the laboratory had not documented the discontinuance of the "Ectoparasites" procedure.
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, patient test records, and interview with testing personnel (TP) #2; the laboratory failed to check and document quality control (QC) reviews for immunohistochemical (IHC), special and differential staining from 2-11-2021 through the date of survey (8-19-2021) by qualified laboratory personnel. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Evaluation of Quality Control Slides by Physicians", which stated: "4. On site dermatopathologists will record all finding and actions on the quality control log. Off site dermatopathologists will communicate via email to the laboratory manager" 2. Review of patient testing results found for four of eight testing dates (03-24-2021, 03-28-2021, 07-16-2021, and 06-30-201) reviewed the laboratory failed to document quality control checks by a dermatopatholgist for immunohistochemical, special, and differential staining performed for the dates identified as identified in the above laboratory policy. 3. Review of the log, "Review of Control Tissue", found QC slide staining checks were performed by technologists and not qualified dermatopathologists for all staining performed from 2-11-2021 through 8-19-2021 (date of survey). 4. On survey date 08-19-2021, at 3:00 pm, TP#2 confirmed quality control records were reviewed by the technologist as outlined in the procedure, "Microscopy Quality Control". 5. Review of the procedure, "Microscopy Quality Control", found the laboratory director delegated the review of quality control slides for IHC, Special and differential stains to technologists not qualified as technical supervisors for histopathology testing. 6. On survey date 08-19-2021, at 3:00 pm, TP#2 confirmed QC checks were not performed and documented by qualified laboratory personnel.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #2; the laboratory failed to have individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart

	for the volume and complexity of testing performed. Findings Include: 1. The laboratory failed to ensure one of six testing personnel were qualified for high complexity histopathology testing. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)

	(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #2; the laboratory failed to ensure one of six testing personnel were qualified for high complexity histopathology testing. Findings Include: 1. Review of educational documentation for one of six testing personnel identified on the CMS-209 failed to meet the minimum education requirements for high complexity histopathology testing. a. TP#3 - Review of educational transcripts provided found TP#3 failed to have the minimum chemistry/biology/medical technology credits in order to meet the educational requirements for high complexity histopathology testing. 2. On survey date 08-19-2021, at 3:00 pm, the above findings were confirmed by TP#2.