Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2117221	01/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Quincy Medical Group-Dermatology	1025 Maine St, Quincy, 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, direct observation and interviews 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. Findings include: 1. The laboratory failed to perform bi-annual method accuracy evaluations for Mohs histopathology testing in 2018 and 2020. See D5217. 2. The laboratory failed to follow the written policy for the proper storage of specimen slides. See D5311. 3. The laboratory failed to accurately document pathology differential staining quality control (QC) records for 3 of 6 patient testing dates reviewed. 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 and interview with testing personnel (TP) #2; the laboratory failed to perform bi-annual method accuracy evaluations for Moh's histopathology testing in 2018 and 2020. Findings Include: Repeat Deficiency 1. The laboratory's policy and procedure manual and proficiency testing records were reviewed for 2018 through 2020. 2. Review of the laboratory's proficiency testing

	policy stated, "Semi-annually, the tech or Risk manager will send two 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." The policy went on to state, "Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." 3. Review of proficiency testing documentation found zero cases were sent out in 2018 and 2020 as outlined in the proficiency testing policy. 4. Review of the laboratory's Moh's case log revealed the laboratory resulted out 859 cases in 2018 and 706 cases in 2020. 5. Interview with testing personnel (TP) #2, on 01-12-2021, at 12:55 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for Moh's histopathology testing in 2018 and 2020 as described in the laboratory proficiency testing policy.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with the testing personnel (TP) #2; the laboratory' failed to follow written policy for the storage of specimen slides. Findings Include: 1. The laboratory's policy and procedure manual was reviewed. 2. The laboratory's policy and procedure manual identified the procedure, "Storage of diagnosed slides", which states "1. Place slides in numerical order oon slide trays 2. Slides are stored on trays until dry. usually 1 week is adequate. 3. Slides are then transferred to the permanent slide file, making sure that rows and drawers are labeled as to contents with lab accession number and year. 4. Slides are kept on location for ten years." 3. During tour of the laboratory facility on 1-12-2021 at 9:50 am patient slides were observed on multiple counters and shelves scattered throughout the laboratory and not stored in the trays for recently drying slides or permanent slide file. 4. On survey date 1-12-2021, at 12:55 pm, TP#2 confirmed the laboratory's policy for specimen slide storage failed to be followed and slides needed be organized and filed in the permanent slide storage bins.
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 testing personnel (TP) #2;

	the laboratory failed to accurately document pathology differential staining quality control (QC) records for 3 of 6 patient testing dates reviewed. Findings Include: 1. The laboratory's QC program policy and documentation was reviewed for 2018 through 2021. 2. The laboratory's QC program policy stated the following in regard to "Reagents": "3. The stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC log." 3. Review of patient testing results for 3 of 6 testing dates (04-24-2019, 10-08-2019, and 02-10-2020) found the documented case number on the "Quality Control Staining" log and the QC slide failed to match. 4. On survey date 01-12-2021, at 12:55 pm, TP#2 confirmed the quality control records documented on the QC logs failed to match the QC slide prepared for 3 of the 6 testing dates reviewed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory records and interview with laboratory testing personnel (TP) #2, the laboratory director failed to provide the overall management and direction to maintain proper laboratory operation. The laboratory director must meet the qualification requirements of 493.1443 and the overall management and direction in accordance with 493.1445. Findings include: 1. The laboratory director (LD) failed to ensure a quality assessment program was maintained and identified failures in chemical/reagent documentation and quality control slide documentation for Moh's histopathology testing. See D6093. 2. The laboratory director (LD) failed to ensure the quality assessment program was maintained to assure the quality of laboratory services provided for 24 of 24 months reviewed. See D6094. 3. The laboratory director failed to ensure the competency policy was maintained 1 of 1 TP that perform the grossing of Moh's histopathology specimens. See D6103.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 testing personnel (TP) #2; the laboratory director (LD) failed to ensure the quality assessment program was maintained as described and identified failures in chemical/reagent documentation and quality control slide documentation for Moh's histopathology testing. Findings Include: 1. The laboratory's quality control program policy and documentation was reviewed for 2018 through 2021. 2. The laboratory's quality control program policy states the following in regard to "Reagents": "1. Reagents must be examined upon arrival for any damage to containers 2. Reagent lot numbers and expiration dates must be recorded. 3. The stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is

	recorded on a QC log." 3. Review of the laboratory policy manual identified the form "Chemical Log" but no completed logs were found for review in the laboratory's records. 4. The laboratory's quality control program failed to identify errors in differential staining quality control documentation. See D5601. 5. On survey date 01-12-2021, at 12:55 pm, TP#2 confirmed the laboratory failed to complete the chemical log form in 2018 through 2021 and correctly document differential staining quality control records as described in the quality control program policy.
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 testing personnel (TP) #2; the laboratory director (LD) failed to ensure the quality assessment program was maintained to assure the quality of laboratory services provided for 24 of 24 months reviewed. Findings Include: Repeat Deficiency 1. Review of the laboratory's policy and procedure manual identified the policy, "Quality Assurance Program", which stated the following: "The Laboratory Director must hold monthly staff meetings. Minutes should be taken and retained as documentation." 2. Review of the quality assurance documents found no documented monthly staff meetings for 18 of 24 months reviewed in 2019 through 2020. 3. Review of monthly quality assurance checklist documentation revealed the laboratory failed to complete the "Monthly Patient Quality Assurance Checklist" form for 24 of 24 months reviewed. 4. On survey date 01-12-2021 at 12:55 pm, TP #2 confirmed the above findings.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #2; the laboratory director failed to ensure the competency policy was maintained 1 of 1 TP that perform the grossing of Mohs histopathology specimens. Findings Include: 1. The laboratory's policy and procedure manual and competency assessment records were review for 2018 through 2020. 2. The policy, "Proficiency testing Competency and CLIA competency assessment", outlined the competency procedure for testing personnel in the specialty of pathology. The policy states the following: "Evaluation and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual sees patient specimens. After the first year, competency assessment must be performed at least annually. Competency assessment can be done throughout the entire year by coordinating it with routine

	practices to minimize impact on workload." 3. Review of competency assessment records for TP#2 found no documented competency assessments in 2018, 20119, and 2020. 4. On survey date 1-12-2021, at 12:55 pm, the above findings were confirmed by TP#2.