

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2117221	<b>(X3) Date Survey Completed</b>  04/25/2018
<b>Name of Provider or Supplier</b>  Quincy Medical Group-Dermatology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and personnel interviews; the laboratory failed to perform bi-annual method accuracy evaluations established by the laboratory for moh's histopathology testing in 2017. Findings Include: 1. 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." 2. Review of proficiency testing documentation found 1 case that was sent out in August of 2017 but no review was documented. An additional 2 cases were sent in November of 2017 but again no review was documented. 3. Interview with testing personnel (TP) #2, on 04-25-2018, at 12:30 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for moh's histopathology testing in 2017 as described in the laboratory proficiency testing policy.</p>
<b>D5409</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to document the discontinuance of 3 laboratory procedures. Findings Include: 1. Review of the laboratory's procedure manual identified the test procedures "KOH examination", "Mycology", and "Tzank Prep" which were put into use on 09-26-2016 by the laboratory director (LD). 2. On survey date, 04-25-2018, at 12:30 pm, testing personnel (TP) #2 confirmed that the laboratory does not perform the above procedures found in the laboratory's procedure manual but the LD failed to document when the tests were discontinued.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to document daily maintenance as described in the laboratory procedure manual for 16 of 16 months reviewed. Findings Include: 1. Review of the laboratory procedure manual identified the policy, "Laboratory Daily Maintenance", which stated: "10. Document that daily maintenance has been completed by initialing daily maintenance log" 2. Review of preventative maintenance documents identified the log, "Daily Routine Maintenance", which failed to be completed in 2017 through the date of survey, 04-25-2018. 3. On survey date 04-25-2018, at 12:30 pm testing personnel (TP) #2 confirmed daily routine maintenance was not documented for 16 of 16 months reviewed.

**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 laboratory personnel; the LD failed to ensure the quality assessment program was maintained to assure the quality of laboratory services provided as 16 of 16 months reviewed failed to have documented staff meetings as described in the quality assurance program. Findings Include: 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 meeting in 2017 through the date of survey, 04-25-2018. 3. On survey date 04-25-2018 at 12:38 pm, testing personnel (TP) #2 confirmed no staff meeting were documented for 16 of 16 months reviewed.