

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2050060	(X3) Date Survey Completed 01/23/2018
Name of Provider or Supplier Rmg Dermatology	Street Address, City, State 885 Roosevelt Rd - Ste 301, Glen Ellyn, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations; review of policies and procedures manuals and maintenance records; and interview, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings: 1. During survey date 01/23/18, the surveyor observed that the laboratory used the following equipment to perform histopathology procedures: a. Microscope b. Microtome c. Fume hood e. Stainer 2. There were no procedures that described how the laboratory maintained the Microtome and Stainer. However, the procedure for the Airfiltronix fume hood describes a series of filters that may be used with the fume hood. However, the laboratory did not define the type of filter used in the fume hood. Nor did the lab define a specific maintenance schedule for changing the filter. 3. There were no records to show that the laboratory performed and maintenance or preventative maintenance on its Microtome, Fume hood, and Stainer. 4. During survey date 01/23/18 at 1:00 PM, the laboratory director confirmed the surveyor's findings.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate</p>

results.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings: 1. Review of personnel records for persons who process histopathology specimens revealed that 1 of 5 testing personnel was educated in a foreign country. However, there was no documentation to show what the U. S. equivalent education is. The documentation submitted to the surveyor only interprets the language. 2. During survey date 01/23/18 at 1:00 PM, the laboratory director confirmed the surveyor's findings.

D6124

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:
Based on direct observations; review of laboratory records; and interview, the procedures for evaluation of the competency of the staff did not include direct observation of performance of instrument maintenance and function checks. Findings: 1. During survey date 01/23/18, the surveyor observed that the laboratory performed histopathology procedures while using the following equipment: Microtome, Microscope, Fume Hood, and Stainer. 2. There was no documentation to show that the laboratory personnel performed maintenance and/or preventative maintenance on its Microtome, Fume Hood, and Stainer. 3. During survey date 01/23/17 at 1:00 PM, the laboratory director confirmed the surveyor's findings.