

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0392965	(X3) Date Survey Completed 04/12/2019
Name of Provider or Supplier Ssm Health Dean Medical Group - N High Point Rd	Street Address, City, State 752 N High Point Rd, Madison, WI	
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
D5217	<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 surveyor review of laboratory dermatopathology records and interview with the laboratory manager, the laboratory has not evaluated the accuracy of Mohs testing twice annually in 2018. Findings include: 1. Review of laboratory dermatopathology records from 2018 show no evidence of twice annual accuracy evaluation for Mohs test results. 2. Email communications with the laboratory manager on April 19, 2019 at 1:26 PM confirmed twice annual accuracy verification of Mohs test results had not been performed in 2018. This is a repeat deficiency previously cited February 12, 2013.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory</p>

manager, the laboratory has not documented cryostat temperature, room temperature, and room percent humidity each day of patient testing to ensure conditions are acceptable for test system operations. Findings include: 1. Review of the "Mohs Laboratory Maintenance Log" and the patient accession log show that cryostat temperatures for two of two cryostats, room temperature, and room percent humidity were not documented for 32 out of 42 days patient testing was performed in 2018 in the dermatopathology laboratory. 2. Email communication with the laboratory manager on April 17, 2019 at 8:41 AM confirms the laboratory maintenance was not documented as required for all of the days patient testing was performed in 2018 in the dermatopathology laboratory to ensure conditions were acceptable for test system operations.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview with the laboratory manager, the laboratory did not document the quality control check on the Hematoxylin and Eosin (H&E) stain each day of patient testing to ensure stain quality. Findings include: 1. Review of the "Mohs Laboratory Maintenance Log" show that Hematoxylin and Eosin (H&E) stain quality control check was not documented for 32 out of 42 days patient testing was performed in 2018 in the dermatopathology laboratory. 2. Email communication with the laboratory manager on April 17, 2019 at 8:41 AM confirms the laboratory did not document stain quality as required for 32 out of 42 days patient testing was performed in 2018 in the dermatopathology laboratory.