

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2105735	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Sheth Dermatology & Mohs Surgery Ctr	Street Address, City, State 9131 West 151 St Street, Orland Park, 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	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interviews with a laboratory representative and the laboratory director (LD); 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 2017, 2018, and 2019. See D5217. 2. The laboratory failed to evaluate mohs histopathology method accuracy evaluations, identify unsatisfactory performance, and document the corrective action taken in 2017 through 2019. See D5221.</p>
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 review of laboratory records and interviews with a laboratory representative and the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for mohs histopathology testing in 2017, 2018, and 2019. Findings Include: 1. Surveyor requested bi-annual method accuracy evaluations for pathology from the laboratory representative on 11-07-2019 at 12:50 pm. 2. Review</p>

of method accuracy evaluations for mohs histopathology testing found only one review was completed each year in 2017, 2018, and 2019. 3. Review of mohs histopathology testing logs revealed 452 mohs cases were resulted by the laboratory in 2017 through 2019. 4. On survey date 11-17-2019 at 4:00 pm the LD confirmed the laboratory failed to perform bi-annual method accuracy evaluations for mohs histopathology in 2017, 2018, and 2019.

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 and interviews with a laboratory representative and the laboratory director (LD); the laboratory failed to evaluate and identify unsatisfactory performance for mohs histopathology method accuracy evaluations and document the corrective action taken in 2017 through 2019. Findings Include: 1. Surveyor requested bi-annual method accuracy evaluations for pathology from the laboratory representative on 11-07-2019 at 12:50 pm. 2. Review of method accuracy evaluations for mohs histopathology testing found the laboratory failed to evaluate 3 of 3 mohs histopathology method accuracy evaluations performed in 2017, 2018, and 2019. 3. Review of the method accuracy evaluation completed in 2018 revealed 1 of 2 mohs histopathology cases reviewed had different diagnosis by the reviewing pathologist than originally reported by the laboratory. Case 1 Original histologic interpretation by the lab after the mohs procedure - Clear of tumor 2nd pathologist histologic interpretation after the mohs procedure - "Minute focus of Sup BCC" 4. Review of proficiency testing records found no corrective action was documented for the discrepancy identified. 5. Review of mohs histopathology testing logs revealed 452 mohs cases were resulted by the laboratory in 2017 through 2019. 6. On survey date 11-17-2019 at 4:00 pm, the LD confirmed the laboratory failed to review mohs histopathology method accuracy evaluations in 2017 through 2019, identify issues, and perform corrective actions.