Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2151836	05/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Concierge Dermatology & Skin Surgery Center	18341 U S Highway 41, L' Anse, MI	

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 the number and severity of the deficiencies cited herein, the Condition: Histopathology was not met. Findings include: 1. The laboratory failed to assess the competency of testing personnel performing tissue specimen grossing and microscopic tissue examinations as part of Mohs surgery. Refer to D5209. 2. The laboratory failed to verify the accuracy of its tissue specimen grossing and microscopic tissue examinations as part of Mohs surgery. Refer to D5217. 3. The laboratory failed to ensure the Hematoxylin and Eosin stain performed with the intended staining characteristics. Refer to D5473. 4. The laboratory failed to follow procedures to perform analytic system quality assessments. Refer to D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to assess the competency of testing personnel performing tissue specimen grossing and microscopic tissue examinations as part of Mohs surgery for 2 (May

	2019 to May 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Control" policy revealed a section stating, "A minimum of 2 random cases are reviewed yearly by a dermatopathologist or Mohs Surgeon. Discrepancies would be addressed in the patient chart." 2. On 5/13/21 at 12:45 pm, the surveyor requested the laboratory's personnel competency assessments, and they were not made available. 3. An interview on 5/13/21 at 12:45 pm with the Mohs Technician confirmed the laboratory did not have competency assessment documentation available.
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 record review and interview with the Mohs Technician, the laboratory failed to verify the accuracy of its tissue specimen grossing and microscopic tissue examinations as part of Mohs surgery for 2 (May 2019 to May 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Control" policy revealed a section stating, "A minimum of 2 random cases are reviewed yearly by a dermatopathologist or Mohs Surgeon. Discrepancies would be addressed in the patient chart." 2. On 5/13/21 at 12:45 pm, the surveyor requested the laboratory's verification of accuracy documentation and it was not made available. 3. An interview on 5/13/21 at 12:45 pm with the Mohs Technician confirmed the laboratory did not have verification of accuracy documentation available.
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 record review and interview with the Mohs Technician, the laboratory failed to ensure the Hematoxylin and Eosin stain performed with the intended staining characteristics for 3 (September, October, and December 2020) of 24 months reviewed. Findings include: 1. A review of the laboratory's "Laboratory Quality Control for Hematoxylin and Eosin" logs revealed the following months lacked documentation of Hematoxylin and Eosin stain performance: a. September 2020 b. October 2020 c. December 2020 2. A review of the laboratory's "Quality Control" policy revealed a section stating, "A control slide will be evaluated each day that a frozen section is prepared. A record of the control slide will be maintained. In this laboratory, this is accomplished by reviewing and recording the staining of a designated slide (QC slides are stored in a container unstained from a previous day's case) each day Mohs is performed. Documented on the Stain Quality Control Log." 3. A review of the laboratory's patient logs revealed 33 patients were tested on days when Hematoxylin and Eosin stain performance had not been documented in the

	months listed above. 4. An interview on 5/13/21 at 12:55 pm with the Mohs Technician confirmed the Hematoxylin and Eosin stain performance documentation was not available for the months listed above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician, the laboratory failed to follow procedures to perform analytic system quality assessments for 2 (May 2019 to May 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance" policy revealed a section stating, "The Quality Assurance Program involves monitoring the facilities, test methods, equipment, reagents, materials, supplies, procedure manual, method verification, equipment maintenance, calibration and calibration verification, control procedures, remedial actions, and maintenance of quality control records." 2. On 5/13/21 at 1:10 pm, the surveyor requested the laboratory's analytic system quality assessment, and it was not made available. 3. An interview on 5/13/21 at 1:10 pm with the Mohs Technician revealed the laboratory's analytic system quality assessment documentation was not available.