Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2158109	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Concierge Dermatology & Skin Surgery	1500 Sand Point Road, Munising, 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
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, the laboratory failed to follow their "Quality Assurance Program" procedure for daily temperature checks, maintenance, and quality control for three out of ten days reviewed when patient testing was performed. Findings: 1. Procedure "Quality Assurance Program" under section "Control Procedures" on page three states "The control procedures set forth in the procedure manual will be followed for each test." Procedure for "Mohs Surgery" states in section 6.1.5 "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." 2. Procedure "Quality Assurance Program" under section "Equipment Quality control for Cryostats" states " 1) Room temperature and humidity is checked and recorded daily. 2) Cryostat temperature range is -20 degrees C to -30 degrees C." and "5) Interior and exterior are cleaned daily using 100% reagent alcohol, while wearing gloves and recorded in the cryostat maintenance log." 3. Procedure "Quality Assurance Program" under section "Equipment Quality Control for the Thermo Scientific" states "1. Stain and reagent solutions are changed daily or as needed and recorded." 4. Review of quality records and logs on ten days of patient testing revealed the following: a. On 03/08/2021, the laboratory did not complete quality control for Hematoxylin and Eosin stain. b. On 11/20/2020, the laboratory did not complete the "Maintenance Record for Cryostats". c. On 11/18 /2019, the laboratory did not complete quality control for Hematoxylin and Eosin stain, the "Maintenance Record for Cryostats", the "Cryostat Temperature Log", the

	"Stainer Maintenance Log", and the "Room Temperature and Humidity Log". 5. The laboratory completed a "Corrective Action Request Form" for the quality control not performed on 03/08/2021. The corrective action listed was "tech will continue to produce daily QC slide from previous day & perform QC prior to first Mohs case." 6. Testing personnel #1 confirmed the findings above at approximately 12:40 PM on August 17, 2021.