Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0194700	02/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Center For Dermatology Laser & Cosmetic Surgery	915 Montgomery Ave, Suite 204, Narberth, PA	

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
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 review of the competency assessment procedure, review of personnel competency assessment records and interview with the laboratory consultant, the laboratory failed to establish a complete competency assessment procedure to assess 1 of 1 pathologist performing Dermatopathology slide examinations in 2019, 2020 and 2021. Findings Include: 1. On the day of survey, 02/24/2021, the laboratory could not provide a complete competency assessment procedure to assess the competency for 1 of 1 pathologist performing Dermatopathology slide examinations in 2019, 2020 and 2021. 2. Review of competency assessment records for 1 of 1 pathologist performing Dermatopathology slide examinations revealed, they were not assessed for the following areas of competency in 2019, 2020 and 2021: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. - Direct observation of performance of instrument maintenance and function checks. - The assessment of problem solving skills. 2. The laboratory consultant confirmed the finding above on 02/24/2021 around 9:30 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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.

	This STANDARD is not met as evidenced by: Based on observation of the Olympus BX 41 microscope and interview with laboratory consultant, the laboratory failed to perform maintenance/calibration on 1 of 1 Olympus BX 41 microscope from 08/17/20219 to 02/03/2021. Findings include: 1. On the day of survey, 02/24/2021, observation of the microscope revealed, 1 of 1 Olympus BX 41 microscope was due for maintenance /calibration on 08/17/2019. 2. The Olympus BX 41 microscope was recently calibrated on 02/03/2021. 3. The laboratory consultant confirmed the finding above on 02/24/2021 around 10:10 am.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of Hematoxylin and eosin (H&E), special and immunohistochemical (IHC) stain quality control (QC) records and interview with the laboratory consultant, the laboratory failed to document QC for Periodic acid-Schiff (PAS) special stains examined in 2019 and 2020. Findings include: 1. The Technical Lab Information on histology stain: H&E, Special stains and Immuno stain QC procedure states, "Upon completion and microscopic evaluation of the controls slide (s) on the H&E stain, special stain or immuno stain the technologist who evaluates the slides(s) must fill out the slide and stain log from each stain and immuno done. The H&E slide used for the control for each day is also noted at the top of the slide and stain log form." 2. On the day of survey, 02/24/2021, review of a sampling of H&E, Special stains and IHC stain QC logs revealed, QC was not performed for the following PSA special stains examined in 2019 and 2020: 2019: -Case#: HFL2020-1259. -Case#: HFL2020-1260. -Case#: HFL2020-1250. -Case#: HFL2020-1218. -Case#: HFL2020-1210. -Case#: HFL2020-1244. 2020: -Case#: HFL2019-002185. -Case#: HFL2019-002189. -Case#: HFL2019-002144. -Case#: HFL2019-002142. -Case#: HFL2019-002143. -Case#: HFL2019-002214. -Case#: HFL2019-002221. -Case#: HFL2019-002266. -Case#: HFL2019-001913. 2. The laboratory examined 39 special stain slides in 2019. 2. The laboratory examined 47 special stain slides in 2020. 3. The laboratory consultant confirmed the findings above on 02/24/2021 around 9:45 am.