Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2022326	07/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin Cancer Institute	1240 S Broad Street, Suite 200, Lansdale, 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 Laboratory procedure manual and interview with testing personnel (TP), the laboratory failed to establish a complete procedure to assess 1 of 2 TP in Histopathology from 07/08/2021 to the date of survey. Findings include: 1) On the day of survey, 07/21/2023 at 10:15am, the laboratory failed to provide a complete written policy that reviews how to assess the competency with the 6 points of CLIA for 1 of 1 histotechnologist performing grossing and inking and for 1 of 1 dermatopathologist performing dermatopathology slide reading from 07/08/2021 to date of survey. 2) Review of 2021-2023 Histotechnologist Competency Assessment records, revealed competency assessments were incomplete due to no evaluation of point #5 (Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency samples). 3) The TP confirmed the findings above on 07/21/2023 around 10:40am.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (Form CMS-209), personnel

	credentials and interview with Testing Personnel (TP), the laboratory failed to ensure that 1 of 3 TP had the minimum qualifications required to perform High Complexity testing from 07/08/2021 to date of survey. Findings include: 1) On the day of survey, 07/21/2023 at 09:18am, review of the credentials for TP #3 (CMS-209) revealed they did not meet the minimum education and experience requirements to perform grossing and inking for dermatopathology from 07/08/2021 to date of survey. 2) The document provided at the time of inspection was an Associate in Applied Science in Medical Assisting and Office Management awarded on 05/04/1997. 3) Interview with TP #3 confirmed they did not have the minimum credits needed to meet the education equivalent to 496.1489(b)(2)(l). 4) TP confirmed the findings above on 07/21/2023 around 10:40am.