Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2127740	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Whalen Dermatology Of Pittsburgh	160 Millers Run Road, Suite 500, Bridgeville, 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 a lack of competency procedure and interview with the Medical Assistant (MA), the laboratory failed to establish a competency procedure to assess 4 of 4 Testing Personnel (TP) who performed testing in Mycology and Parasitology from 7/27/2021 to the day of the survey. Findings Include: 1. On the day of the survey, 07/12/2023 at 11:52 AM, the laboratory could not provide a competency assessment procedure to assess competency for 4 of 4 TP (CMS 209 Personnel #1, #2, #3, #4) who performed fungal and scabies examinations from 2021 to 2023. 2. The laboratory failed to provide any fungal and scabies competency assessment record for TP#1, TP#2, TP#3, and TP#4 (CMS 209). 3. MA confirmed the findings above on 07/11/2023 around 12:54 PM.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a lack of Quality Control (QC) log and interview with the Medical Assistant (MA), the Laboratory Director (LD) failed to establish and maintain QC for Scabies testing in Parasitology from 07/15/2021 to the day of the inspection. Findings include: 1. On the day of the survey, 07/12/2023 at 12:24 PM, the laboratory failed to provide QC procedure for the scabies testing in Parasitology. 2. The laboratory failed to provide QC documentation for scabies testing from 2021 to the day of the survey. 3. MA confirmed the above findings on 07/12/2023 at 12:54 PM.