

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2127740	(X3) Date Survey Completed 06/23/2025
Name of Provider or Supplier Whalen Dermatology Of Pittsburgh	Street Address, City, State 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on policy and record reviews, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document temperatures to ensure proper storage of mycosel agar plates and accurate and reliable test reporting of mycology examinations for 22 of 52 weeks in 2024 and 14 of 24 weeks in 2025. Findings include: 1, The laboratory's Procedure for Fungal/Dermatophyte collection states: " Clinical Consultant will gently press patient sample(skin scrapings) on to the mycosel agar plate. Incubate at room temperature (59-86F). Incubate for minimum of 2 weeks." 2. On the day of survey, 06/23/25 at 1:30 pm, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document the following temperatures to ensure proper storage of mycosel agar plates and accurate and reliable test reporting of mycology examinations in 2024 and 2025: - Room temperature (laboratory's acceptable range 59 to degrees Fahrenheit): 22 of 52 weeks in 2024 and 14 of 52 weeks in 2025 - Refrigerator temperature (laboratory's acceptable range 36-46 degrees Fahrenheit) : 22 of 52 weeks in 2024 3. The hours of laboratory testing are Monday-Thursday 08:00 am to 04:30 pm and Friday 08:00 am to 12:30 pm (CMS 116). The laboratory could not provide documentation of temperatures taken on days the laboratory was closed. 4. The laboratory performed 60</p>

mycology examinations in 2024 (CMS 116 estimated annual volume). 5. The LD confirmed the above findings on 06/23/25 at 2:30 pm.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Control (QC) log, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to document a positive and negative control each day of patient testing for Scabies (Parasitology) examinations performed for 2 of 2 years from 7/12/2023 to the day of the survey.

Findings include: 1. On day of survey, 06/23/2025 at 01:25 pm, the laboratory failed to provide documentation of a positive and negative control each day of patient testing for Scabies examinations performed for 2 of 2 years from 7/12/2023 to 6/23/2025. 2. The laboratory performed 60 parasitology examinations in 2024 (CMS 116 estimated annual volume). 3. The LD confirmed the above findings on 06/23/25 02:25 pm.