

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2127740	(X3) Date Survey Completed 07/15/2021
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the medical assistant, the laboratory failed to establish a competency assessment procedure to assess the competency of 4 of 4 testing personnel (TP) performing dermatophyte test medium (DTM) screening, Potassium hydroxide (KOH) microscopic examinations and scabies microscopic examination from 2019 to the day of survey. Findings include: 1. On the day of survey, 07/15/2021, the laboratory could not provide a competency assessment procedure to assess the competency of 4 of 4 TP performing DTM screenings, KOH microscopic examinations and scabies microscopic examination from 07/15/2019 to 07/15/2021. 2. Review of records revealed in 2019 and 2020 competency assessment for 4 of 4 TP were not performed. 3. Review of 2021 Competency assessment records for KOH and scabies microscopic examinations performed for 4 of 4 TP revealed, competencies were not assess for each test separately. 4. The medical assistant confirmed the findings above on 07/15/2021 around 12:45 pm.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory records and interview with the medical assistant, the laboratory failed to document test requisitions for potassium hydroxide (KOH) and scabies microscopic examinations from 2019 to the day of survey. Findings include: 1. On the day of survey, 07/15/2021, the laboratory could not to provide test requisitions for KOH and scabies microscopic examinations performed from 07/15/2019 to 07/15/2021. 2. The medical assistant confirmed on 07/15/2021 around 1:15 pm, that verbal orders were made for KOH and scabies microscopic examinations, but they were not documented.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records and interview with the medical assistant, the laboratory failed to check and document each batch or shipment of the Hardy Diagnostics Mycobiotic agar for its ability to support growth, select or inhibit specific organisms (end user QC) from 2019 to the date of survey. Findings Include: 1. On the day of survey, 07/15/2021 review of QC records revealed, the laboratory did not perform end user QC on the Hardy Diagnostics Mycobiotic agar used for dermatophyte test medium screening from 07/15/2019 to 07/15/2021. 2. The dermatophye screening policy did not mention specific media QC procedures. 2. The medical assistant confirmed the findings above on 07/15/2021 around 1:00 pm.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the quality assurance (QA) policy and interview with the medical assistant, the laboratory director failed to ensure quality assessment (QA) programs were assessed and maintained bi annually to assure the quality of laboratory services provided in 2020 and 2021. Findings Include: 1. The Quality Assurance policy states, Procedure: Quality control. #6. "A quality assessment will be done bi-annually by the laboratory director. 2. On the date of survey, 07/15/2021, the laboratory could not provide QA activities performed bi annually in 2020 and 2021. 3. The medical assistant confirmed the findings above on 07/15/2021 around 12:50 pm.