

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2005548	(X3) Date Survey Completed 04/09/2024
Name of Provider or Supplier Ohio Skin Cancer Institute	Street Address, City, State 5040 Forest Dr, Suite 200, New Albany, OH	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager, the laboratory failed to conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity Mohs testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 572 out of 572 patients tested in the subspecialty of Histopathology from 01/01/2022 through 12/31/2023. Findings Include: 1. The Inspector requested the blind TAV policy and procedure from the Laboratory Manager. The policy stated the following: "...lab personnel is required to send slides from no less than 2 cases at least 2 times per annum for slide quality review to another mohs surgeon or dermatopathology physician..." 2. The Inspector requested the blind TAV results for the years 2022 and 2023 from the Practice Manager. 3. The Laboratory Manager confirmed the laboratory did not follow the policy and procedure for blind TAV activities at least twice annually for the high complexity Mohs testing procedures performed in the years 2022 and 2023 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/09/2024 at 2:34 PM.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)</p>

The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Manager, the laboratory failed to ensure the quality control programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for the moderate complexity potassium hydroxide (KOH) and scabies testing procedures in the subspecialties of Mycology and Parasitology, respectively. This deficient practice had the potential to affect 9 out of 12 patients tested in the subspecialties of Mycology and Parasitology from 01/01/2022 through 04/09/2024. Findings Include: 1. The Inspector requested the laboratory's KOH and scabies quality control policy and procedure from the Practice Manager. Review of the policy found the following statement: "...Quality control (QC) slide must be performed with each patient test... Two slides per patient will serve as internal controls..." 2. The Inspector requested the laboratory's quality control data for the years of 2022, 2023 and 2024 from the Practice Manager. Review of the quality control data found the following: KOH "Date Result +/- Control... 08/30/22 positive 09-07-22 + B/L cheeks 04/24/23 + left wrist... 11/23/2023 - L superior... 12/01/2023 no hyphae L hip... 12/6/23 no hyphae central back...2/12/24 - no hyphae left ... breast" Scabies "Date Result +/- Control... 08-25-22 Neg. Rt ankle 12/6/23 - lower R back..." 3. The Practice Manager confirmed the laboratory failed to follow the quality control policy and procedure for KOH and scabies testing procedures for 9 out of 12 patients tested from 01/01/2022 through 04/09/2024 in the subspecialties of Mycology and Parasitology and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/09/2024 at 2:34 PM.