

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2298617	(X3) Date Survey Completed 11/18/2025
Name of Provider or Supplier The Dermatology Group	Street Address, City, State 5184 Socialville-Foster Road, Mason, 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 General Supervisor (GS), the laboratory failed to conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 78,000 out of 78,000 patients tested in the subspecialty of Histopathology from 12/01/2023 through 11/18/2025. Findings Include: 1. Review of "Dermpro Dermatopathology Method Accuracy Verification Form (Analytical Peer Review)" forms documenting TAV for December 2023 through October 2025, revealed the diagnoses for interpretations were provided to the peer reviewer. 2. Review of the policy and procedure titled, "Quality Assurance and Improvement Program" approved via signature and date by the Laboratory Director on 03/17/2023, did not find any mention of blind TAV. 3. The Inspector requested 2023, 2024 and 2025 blind TAV results for the Histopathology test system from the GS. The GS confirmed the laboratory did not perform blind TAV and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/18/2025 at 3:30 PM.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform</p>

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the General Supervisor (GS), the Technical Supervisor (TS) failed to evaluate the competency of performing high complexity test procedures and reporting test results promptly, accurately and proficiently in the subspecialty of Histopathology. This affected one Testing Personnel (TP) #1 of seven TPs reviewed for competency. Findings Include: 1. Review of the laboratory's Form CMS-209 revealed revealed seven individuals listed and qualified as TP by the Laboratory Director via signature and date on 11/05/2025. Further review of the CMS-209 revealed the LD was listed as the sole TS. 2. Review of the laboratory's policy and procedure titled, "Orientation and Competency Verification Program", approved by the Laboratory Director on 04/25/2017, found the following statement: "2. RESPONSIBILITIES: The Laboratory Director will ensure that all personnel are initially trained, monitored every 6 months and annually thereafter for competency in all areas of Histopathology." 3. Review of the laboratory's competency assessment documentation, provided on the date of the inspection, did not find an annual 2024 assessment for TP #1. This deficient practice had the potential to affect all patients tested by TP #1 in 2024. 4. Review of the laboratory test records revealed TP#1 has been completing high complexity testing procedures on patient specimens. 5. An interview on 11/18/2025 at 2:15 PM, with the GS, confirmed the 2024 annual competency assessment was not performed for TP#1 and TP #1 has been completing high complexity testing procedures.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and an interview with the General Supervisor, the laboratory failed to ensure staff met the qualification requirements of 493.1489 for high complexity testing. This affected one Testing Personnel (TP) #5 out of seven TPs reviewed for qualifications. Findings Include: 1. The laboratory failed to ensure TP #5 met the high complexity testing personnel qualification requirements. (Refer to D6171)

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the General Supervisor (GS), the laboratory failed to ensure staff met the qualification requirements of 493.1489 for high complexity tissue biopsy grossing test procedures performed in the subspecialty of Histopathology. This affected one Testing Personnel (TP) #5 out of seven TPs reviewed for qualifications. Findings Include: 1. Review of the laboratory's Form CMS-209, found seven individuals listed and qualified as TP by the Laboratory Director via signature and date on 11/05/2025, to perform high complexity tissue grossing test procedures. 2. Review of education documents provided on the date of the inspection revealed TP #5, hired 07/31/2023, possessed an Associate of Applied Science, which did not meet the required number of credit hours in chemistry, biology and/or medical laboratory technology and does not meet the minimum TP qualifications for high complexity laboratory testing. This deficient practice had the potential to affect all patient tissue specimens grossed by TP #5 from the date of hire 07/31/2023, through 11/18/2025. 3. Review of the laboratory test records revealed TP #5 had completed tissue grossing procedures on patient specimens since the hire date of 07/31/2023 through 11/18/2025. 4. An interview on 11/18/2025 at 2:00 PM, with the GS confirmed TP #5 did not meet the TP qualification requirements and had been performing high complexity testing procedures.