

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0911386	(X3) Date Survey Completed 09/30/2025
Name of Provider or Supplier Pinnacle Dermatology Brighton	Street Address, City, State 6888 Grand River Avenue, Brighton, MI	
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
D0000	A recertification survey was performed on September 30, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with testing personnel #2, the laboratory failed to ensure its Vintage Bluing staining reagent was not used beyond expiration dates for three (6/30/25 to 9/30/25) of three months since the reagent expired on 6/30/25. Findings include: 1. The surveyor observed an expired bottle of Vintage Bluing with the expiration date of 6/30/25 on 9/30/25 at 9:01 am. 2. A review of the laboratory's reagent tracking log revealed a lack of information to show the expired bottle was taken out of use at this laboratory after it expired. 3. An interview on 9/30/25 at 9:06 am with testing personnel #2 confirmed the bottle of Vintage Bluing had expired.</p>
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p>

This CONDITION is not met as evidenced by:

. Based on record review and a lack of documentation, testing personnel #2 failed to meet high complexity testing personnel qualifications for the tissue specimen grossing performed. 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) (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 a lack of documentation, testing personnel #2 failed to meet high complexity testing personnel qualifications for the tissue specimen grossing performed for 14 (July 2024 to September 2025) of 14 months since testing personnel #2 started testing. Findings include: 1. A review of testing personnel #2's training and competency records revealed both training and competency were completed on 7/3 /24. 2. A review of testing personnel #2's education documentation showed transcripts. The transcripts failed to include the name of the institution, at least 60

completed semester hours, at least six semester hours of chemistry, at least 24 semester hours of science courses, and either completion of a training program approved or accredited by the ABHES or the CAAHEP or at least three months documented laboratory training in histopathology testing. 3. The surveyor requested additional institutional information, educational credits, training program information or documentation of applicable training on 9/30/25 at 10:21 am and it was not made available. 4. The laboratory was granted seven days to provide the missing qualification records, and none were provided.