

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0688063	(X3) Date Survey Completed 02/13/2024
Name of Provider or Supplier Psoriasis And Eczema Treatment Center	Street Address, City, State 833 Michigan St Ne, Suite 102, Grand Rapids, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to document the evaluation of unsatisfactory results and corrective action taken for its histopathology twice annual verification of accuracy testing for 1 (1st event of 2023) of 4 testing events reviewed. Findings include: 1. A review of the laboratory's histopathology "Proficiency Test Year 2023" documentation revealed the laboratory's result was "Atypical Nevus" and the reference laboratory's result for the same case was "Malignant Melanoma In Situ, involving peripheral margins." 2. The surveyor requested the evaluation and corrective action for the testing event listed above with differing results on 2/13/24 at 10:07 am and it was not made available. 3. An interview on 2/13/24 at 10:46 am with the Office Manager confirmed the laboratory had not performed and documented the evaluation of its histopathology twice annual verification of accuracy.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

. Based on record review and interview with the Office Manager, the laboratory failed to ensure staff performing Technical Consultant duties were qualified. Refer to D6033.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and a lack of documentation, the laboratory failed to ensure staff performing Technical Consultant duties were qualified as Technical Consultants for 2 ("MB" and "MD") of 4 personnel performing testing personnel competency assessments. Findings include: 1. A review of the laboratory's testing personnel competency records for its Potassium Hydroxide and Scabies preparations revealed two individuals with the initials "MB" and "MD" had performed competency assessments for testing personnel in 2023 for Testing Personnel #4 and #5. No individuals listed on Form CMS-209 had these initials. 2. The surveyor requested documentation of qualifications for "MB" and "MD" showing they had met the Technical Consultant requirements on 2/13/24 at 10:10 am and it was not made available. 3. The laboratory was given an additional 7 days to provide the missing documentation and it was not provided.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

. Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel were qualified prior to performing moderately complex testing. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel were qualified prior to performing moderately complex testing for 1 (Testing Personnel #4) of 5 testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel qualifications revealed a lack of documentation for Testing Personnel #4 to meet moderate complexity testing personnel qualification requirements at 493.1423. 2. The surveyor requested additional qualification documentation for Testing Personnel #4 on 2/13/24 at 10:14 am and it was not made available. 3. The laboratory was provided and additional 7 days to provide the missing qualification documents and they were not made available.