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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D2261543 | (X3) Date Survey Completed 01/24/2025 |
| Name of Provider or Supplier Dermatology & Aesthetics Of Wicker Park Pllc | Street Address, City, State 1733 N Harlem Ave, Chicago, IL | |
| 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 |
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| 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 policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to follow the established competency policies by failing to perform competency assessments for four of four testing personnel (TP) performing microscopic Potassium Hydroxide (KOH) wet mount testing from the beginning of testing on 03/27/2023 to the date of survey, 01/24/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Competency and CLIA competency assessment", which stated, "Evaluation and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual sees patient specimens. After the first year, competency assessment must be performed at least annually." 2. Review of laboratory policies and procedures revealed the policy titled, "Personnel Assessment", which stated, "CLIA guidelines require the semiannual assessment of personnel competency during the first year of test performance for Moderate or High Complexity testing. Thereafter, evaluation must be performed at least annuallyPersonnel competency must be assessed by the Laboratory Director or Technical Consultant and will be an on-going process at this facility." 3. Review of laboratory records found no documented competency assessment records for four of four TP performing KOH wet mounts from the beginning of testing on 03/27/2023 to the date of survey, 01/24/2025. 4. Interview with the laboratory representative on 01/24/2025, at 9:50 am, confirmed the</p> |

laboratory failed to follow the established competency policies by failing to perform competency assessments for four of four TP performing KOH wet mounts in the specialty of microbiology.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to perform bi-annual method accuracy evaluations for microscopic Potassium Hydroxide (KOH) wet mount testing from the beginning of testing on 03/27/2023 to the date of survey, 01/24/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "MYCOLOGY", which stated, "This lab has joined a proficiency testing program with The American Proficiency Testing Institute [API]. Membership receipt attached. This lab will have reviews done at least bi-annually. Results will be documented in manuals." 2. Review of laboratory records found no documented API Membership receipt. 3. Review of laboratory records found no documented bi-annual method accuracy evaluations for KOH wet mount testing from the beginning of testing on 03/27/2023 to the date of survey, 01/24/2025. 4. Interview with the laboratory representative on 01/24/2025, at 9:48 am, confirmed that the laboratory was not enrolled in API proficiency testing nor did the laboratory have any documented bi-annual method accuracy evaluations for KOH wet mount testing in the specialty of microbiology.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to follow policies and procedures regarding patient microscopy logs as described in the laboratory's procedure for three of three microscopic Potassium Hydroxide (KOH) wet mount patient testing reports reviewed. Findings include: 1. Review of laboratory policies and procedure revealed the procedure titled, "KOH examination", which stated, "All KOH [examinations] will be logged in the KOH log book with the patient name and the results will be logged after review." 2. Review of laboratory policies and procedures revealed a blank patient logbook example titled, "KOH LOG". 3. Review of laboratory records found the laboratory failed to utilize the KOH patient logbook for three of three KOH patient reports reviewed (medical record numbers: MM0000054488, AC51158008, and MM0000171416) in the specialty of

microbiology. 4. Interview with laboratory representative on 01/24/2025, at 9:53 am, confirmed the laboratory failed to follow policies and procedures regarding patient KOH microscopy logs.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(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;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the technical consultant (TC) failed to address the training needs for four of four testing personnel (TP) performing microscopic Potassium Hydroxide (KOH) wet mount testing in the specialty of microbiology from the beginning of testing on 03/27/2023 to the date of survey, 01/24/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Personnel Assessment", which stated, "Training must be documented prior to reporting patient test results." 2. Review of laboratory records found no documented training for four of four TP performing microscopic KOH wet mount testing in the specialty of microbiology. 3. Interview with the laboratory representative on 01/24/2025, at 9:50 AM, confirmed the TC failed to address the training needs for four of four TP performing microscopic KOH wet mount testing from the beginning of testing on 03/27/2023 to the date of survey, 01/24/2025.