

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2138026	(X3) Date Survey Completed 01/19/2024
Name of Provider or Supplier Aspirus Dermatology Clinic	Street Address, City, State 1901 Westwood Center Boulevard, Wausau, WI	
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
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews, the technical consultant did not document competency assessment for three of three testing personnel responsible for potassium hydroxide (KOH) testing in the laboratory in 2023. Findings include: 1. Review of competency assessments for the laboratory showed no documentation of competency assessment for KOH testing in the laboratory for 2023. 2. A telephone interview with the technical consultant on January 19, 2024, at 12:15 PM confirmed the technical consultant was responsible for competency assessment of the testing personnel performing KOH testing in the laboratory. During the interview the technical consultant stated they would email the Wisconsin State Agency (SA) surveyor the competency assessment records for KOH testing. 3. On January 24, 2024 at 2:09 PM via email the Wisconsin State Agency (SA) surveyor requested competency assessment documentation for KOH testing personnel. As of January 30, 2024, 3:16 PM, no documentation of competency assessment for KOH testing personnel was received by Wisconsin SA surveyor. 4. A telephone interview with the laboratory director on February 1, 2024, at 12:20 PM, the laboratory director confirmed the technical consultant did not document competency assessment for testing personnel performing for KOH in 2023.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) forms, laboratory records and interviews, the laboratory director has not provided overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The laboratory director was not aware of their responsibility for oversight of laboratory performed potassium hydroxide (KOH) testing. See D6079. 2. The laboratory director did not specify, in writing, the responsibilities and duties of the technical consultant. D6107

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Clinical Laboratory Improvement Amendments (CLIA) ASPEN Web federal database and Laboratory Personnel Report Center for Medicare and Medicaid Services (CMS)-209 form and interviews with the laboratory director, histotechnologist and organization personnel, staff A and staff B, the laboratory director has not provided overall management and direction for one of one new tests, Potassium Hydroxide (KOH), in the laboratory. Findings include: 1. Review of CLIA ASPEN Web federal database showed the subspecialties of mycology and parasitology were added to Clinical Laboratory Improvement Amendments (CLIA) number 52D2138026 on March 7, 2023 by staff B via email communication with the state agency. 2. Review of Laboratory Personnel Report, CMS-209, submitted on January 8, 2024, showed no technical consultant identified and no moderate complexity testing being performed. 3. Interview with the laboratory histotechnologist, staff A, on January 19, 2024, at 10:30 AM, stated "the laboratory director was unsure if KOH testing was being performed under CLIA #52D2138026 or if the dermatologists had their own provider performed microscopy certificate at this location." 4. Interview with Aspirus organization personnel, staff B, on January 19, 2024, at 11:54 AM confirmed KOH testing is performed under CLIA # 52D2138026 as of March 7, 2023, and the laboratory director was not made aware of this change. 5. Interview via telephone with the laboratory director on February 1, 2024, at 12:20 PM confirmed the the laboratory director was not aware KOH testing was under Aspirus Dermatology Clinic (52D2138026) and that the laboratory director was to provide management of KOH testing in the laboratory.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Laboratory Personnel Report, Centers for Medicare and Medicaid Services (CMS)-209, and interviews, the laboratory director did not specify, in writing, the responsibilities and duties for one of one technical consultant identified. Findings include: 1. Review of the Laboratory Personnel Report, Form CMS-209, submitted on January 8, 2024, prior to the survey, showed no technical consultant had been identified by the laboratory. 2. Review of the Laboratory Personnel Report, Form CMS-209, submitted on January 22, 2024, after the survey, showed a technical consultant identified by the laboratory. 3. Interview with the technical consultant on January 19, 2024, at 12:15 PM confirmed they were the technical consultant for potassium hydroxide (KOH) testing in the laboratory. 4. Interview with the laboratory director via telephone on February 1, 2024, at 12:20 PM confirmed the laboratory director had not specified, in writing, the responsibilities and duties for the technical consultant.