Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2174831	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ahc- Menomonee Falls- Dermatology	N84 W16889 Menomonee Ave, Menomonee Falls, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on surveyor review of electronic medical records and interview with the laboratory director (staff A), the laboratory did not maintain reports of gross tissue examination results from the Dermpath Diagnostics reference laboratory for one of one record reviewed. Findings include: 1. Review in the electronic medical record of the dermatopathology reports for patient 1 showed no evidence of the gross tissue examination results completed at the reference laboratory (Dermpath Diagnostics) that performed grossing and the technical component of slide preparation. 2. Interview with the laboratory director on August 16, 2023, at 11:15 AM confirmed the laboratory did not retain the gross tissue examination reports received from Dermpath Diagnostics for the dermatopathology diagnostic slides read by staff A.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 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 interview with the laboratory director, the director has not provided overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The director denied responsibility for oversight of laboratory performed potassium hydroxide (KOH) testing. See D6079. 2. The director did not ensure the laboratory established and maintained a quality assurance program. See D6094. 3. The director did not ensure the laboratory developed procedures for or evaluated competence of testing personnel. See D6103. 4. The director did not ensure procedures were available for all staff that performed testing. See D6106.
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 reapportions 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 current Centers for Medicare and Medicaid Form 'Application for Certification' (Form CMS-116) and interview with the laboratory director, the director denied responsibility for oversight of laboratory performed potassium hydroxide (KOH) testing, one of two tests performed by the laboratory. Findings include: 1. Review of the Form CMS-116 submitted to the Wisconsin State Agency on October 31, 2019, showed the laboratory applied for a Provider Performed Microscopy Procedures (PPM) certificate with staff A as the laboratory director. The application showed the laboratory expected to perform an estimated twenty KOH preparations annually. Staff A signed the form on September 13, 2019. 2. During an interview with the laboratory director (staff A) on August 16, 2023, at 11:00 AM the director stated they were not responsible for KOH testing in the laboratory.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of electronic medical records and interview with the laboratory director, the director did not ensure a quality assessment program was established to identify failures in quality as they occurred. Findings include: 1. Review of the 'Derm Surgical Pathology Send Out' record for patient 1 showed the gross description of the specimen was recorded as 1 cm (centimeter) excised tan

	colored skin. 2. During an interview with the laboratory director (staff A) on August 16, 2023, at 11:00 AM, the director confirmed the tissue measurements in the gross description on the report did not correlate with the size of the tissue sample on the slides. The director also stated staff were entering the same size (1 cm) "for every human" for the gross description. Further interview confirmed the director had not ensured the laboratory established a quality assessment program to ensure results entered in the medical record were accurate.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on surveyor interview with the laboratory director and lack of records, the director did not ensure the laboratory developed policies and procedures or that competency evaluations were performed for four of four individuals that performed potassium hydroxide (KOH) testing of dermatologic specimens. Findings include: 1. Requested competency evaluation records were not available during the survey. 2. Interview with the laboratory director on August 16, 2023, at 11:00 AM confirmed the director had not performed competence evaluations of the four staff performing KOH testing.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor interview with the laboratory director and lack of procedures, the director did not ensure that an approved procedure manual was available to personnel for two of two tests performed in the laboratory. Findings include: 1. Procedures were requested but not available for Potassium Hydroxide (KOH) testing of dermatological samples or for dermatopathology diagnostic slide reading. 2. Interview with the laboratory director (staff A) on August 16, 2023, at 11:00 AM confirmed procedures were not available for either KOH testing or the diagnostic reading of dermatopathology slides.