Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2174831	05/15/2024
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 clinic manager, staff A, the laboratory did not retain reports of gross tissue examination results from Dermpath Diagnostics reference laboratory for two of four records reviewed. Findings include: 1. Review of the electronic medical record for dermatopathology reports for patient 1, patient 2, patient 3 and patient 4 showed no evidence of gross tissue examination results completed at the reference laboratory (Dermpath Diagnostics) that performed grossing and the technical component of slide preparation for patient 2 and patient 3. 2. Interview with staff A on May 15, 2024, at 11:35 AM confirmed the laboratory did not retain the gross tissue examination reports received from Dermpath Diagnostics for the dermatopathology diagnostics slides read for each patient tested.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the clinic manager, staff A, the laboratory did not establish a written policy or procedure to assess employee competency for one of one test performed. Findings include: 1. Review of the laboratory procedure manual showed no evidence of a procedure or policy for competency assessment pertaining to potassium hydroxide (KOH) testing. 2. Interview with staff A on May 15, 2024, at 1045 AM confirmed the laboratory had not established a written policy or procedure for assessment of employee competency.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, laboratory procedures and interview with the clinic manager, staff A, the laboratory did not establish a written policy or procedure for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system for two of two tests performed. Findings include: 1. Review of laboratory records showed a form "Menomonee Falls DermPath Diagnostics Report Monthly Quality Assurance" that included chart reviews to ensure all patient information was accurate. 2. Review of the laboratory procedure manual showed no evidence of a procedure or policy for quality assessment that was being performed to include how to monitor, assess and correct problems as identified. 3. Interview with staff A on May 15, 2024, at 1045 AM confirmed the laboratory had not established a written policy or procedure to monitor, assess and correct problems identified in the analytic system.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of laboratory procedures and records and interview with the clinic manager, staff A, testing personnel did not document microscope maintenance for sixteen of nineteen weeks in 2024 per the procedure. Findings include: 1. Review of the "Microscope Maintenance Log Instructions" showed testing personnel were to perform microscope maintenance weekly, recording the date and initials of the personnel performing the maintenance. 2. Review of the Dermpath slide log showed weekly entries into the log for microscope slide reading between January 1, 2024, and May 15, 2024. 3. Review of the "Microscope Maintenance Log" showed documentation of microscope maintenance on April 15, 2024, April 18, 2024, (April 15 and April 18 were in the same week) May 2, 2024, and May 9, 2024. Further review showed no additional documentation of microscope maintenance. 4. Interview with staff A on May 15, 2024, at 10:50 AM confirmed testing personnel did not

	document microscope maintenance per the procedure in 2024. Item 2 Based on surveyor review of laboratory procedures and records and interview with the clinic manager, staff A, testing personnel did not document quality control (QC) for the potassium hydroxide (KOH) testing on one of one new KOH lots per the procedure. Findings include: 1. Review of the KOH testing procedure stated QC to check for contamination was performed on the KOH with each new lot and shipment. 2. Review of laboratory records showed no documentation that QC had been performed on the current log of KOH being used for patient testing. 3. Interview with staff A on May 15, 2024, at 10:55 AM confirmed testing personnel did not document QC on KOH being used for patient testing.