

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D1003929	<b>(X3) Date Survey Completed</b>  04/06/2021
<b>Name of Provider or Supplier</b>  Aurora Health Center Marinette	<b>Street Address, City, State</b>  4061 Old Peshtigo Rd, Marinette, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the technical consultant, the laboratory had no evidence the laboratory director approved and signed the Alcor Scientific iSED analyzer procedure before the laboratory tested patient samples with the analyzer. Findings include: 1. Review of laboratory records showed the laboratory started patient testing with the iSED analyzer on June 16, 2020. 2. Review of the laboratory's Alcor Scientific iSED procedure showed the laboratory director approved and signed the procedure on July 15, 2020. The laboratory had no previous versions to show the director had approved the procedure before June 16, 2020. 3. Interview with the technical consultant (Staff A) on April 6, 2021 at 1:00 PM confirmed the laboratory had no documented evidence to show the laboratory director had approved, signed, and dated the procedure prior to use.</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of the Alcor Scientific iSED analyzer in the laboratory, and interview with the technical consultant, the</p>

laboratory tested two patients with expired reagents on the analyzer in March 1 and 2, 2021. Findings include: 1. Review of laboratory maintenance records for the iSED analyzer showed Wash Solution lot 03/2020 was in use in February 2021 and expired on February 28, 2021. The records showed no lot changes documented in March 2021. Records showed the laboratory tested two patients using the iSED analyzer on March 1 and 2, 2021. 2. Observation of the Wash Solution on the iSED analyzer on April 6, 2021 at 1:00 PM showed the lot number in use was 01/2021. The bottle showed an open date of 3/3/21 and expiration date of 12/21. 3. Interview with the technical consultant on April 6, 2021 at 1:00 PM confirmed the laboratory tested two patients with the iSED analyzer with expired wash solution on March 1 and 2, 2021.