

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0880249	<b>(X3) Date Survey Completed</b>  02/02/2022
<b>Name of Provider or Supplier</b>  A2c1 Aurora Health Center - New Berlin	<b>Street Address, City, State</b>  14555 W National Ave Ste 115, New Berlin, 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>PROCEDURE MANUAL 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 procedures and interview with the technical consultant, two of three procedures reviewed were not signed by the current laboratory director. Findings include: 1. Review of three laboratory procedures showed no evidence the current laboratory director had reviewed or approved the procedures for two new test systems, the Alcor miniiSED analyzer and Sure-Vue hCG (human chorionic gonadotropin) test. The procedure for microscopic examination of urine showed the current laboratory director approved the procedure on December 24, 2020. 2. Interview with the technical consultant through email on February 2, 2022 at 2:16 and 4:54 PM confirmed the current laboratory director had not approved the procedures for the Alcor miniiSED analyzer or Sure-Vue hCG test.</p>