

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0670794	(X3) Date Survey Completed 09/19/2022
Name of Provider or Supplier Uw Eau Claire Student Health Service	Street Address, City, State Crest Wellness Center, Eau Claire, 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
D5407	<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 testing personnel, the laboratory director did not approve, sign, and date the Cepheid GeneXpert Polymerase Chain Reaction (PCR) procedure before testing personnel used the procedure for patient testing in May 2021. Findings include: 1. Review of the "GeneXpert Xpress SARS-CoV-2 by PCR" procedure showed no evidence the laboratory director approved the procedure. 2. Interview with testing personnel (staff A) on September 19, 2022 at 2:00 PM confirmed the director had not signed and dated the "GeneXpert Xpress SARS-CoV-2 by PCR" procedure before testing personnel used the procedure for patient testing in May 2021.</p>