

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0670794	(X3) Date Survey Completed 11/04/2024
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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), email correspondence with the technical consultant, and interview with the technical consultant, the laboratory director did not ensure compliance with regulations requiring notification to Health and Human Services (HHS) or its designee no later than thirty days after changing laboratory directors for one of one new laboratory directors. Findings include: 1. Review of the Form CMS-116 retrieved from Aspen Web CLIA database showed the laboratory director was Kimberly Frodl. 2. Email correspondence with the technical consultant on October 21, 2024, at 9:40 AM stated the new laboratory director was Laura Bentley. Further correspondence stated Dr. Bentley started as the laboratory director in June or July 2024. 3. Review of the Form CMS-116 submitted by the laboratory prior to the survey showed the laboratory director was Laura Bentley. 4. Interview with the technical consultant on November 4, 2024, at 10:15 AM confirmed Dr. Bentley became the laboratory director on July 29, 2024, and the laboratory did not notify HHS or its designee within thirty days of changing the laboratory director.</p>