

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0680547	(X3) Date Survey Completed 02/27/2019
Name of Provider or Supplier Creighton University Student Health Services	Street Address, City, State Harper Center #1034, Omaha, NE	
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
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</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. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and an interview with testing personnel at 1:45 PM on 2/27/2019, the laboratory failed to document the approval of the procedure manual by the current laboratory director. Findings are: 1. Review of the laboratory procedure manual used by the laboratory revealed no signature of the current laboratory director. The laboratory director started on September 30, 2016. 2. Interview with testing personnel revealed the laboratory director had not given written approval of the procedure manual.</p>