Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2156054	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier University Of New England	**Street Address, City, State** 716 Stevens Avenue, Portland, ME	

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
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with Lab Director (LD), the laboratory director failed to provide an approved procedure manual prior to testing patient samples. Findings include: 1. Record review of the laboratory's documentation on 10/5/2022 revealed no procedure manual for testing. 2. Staff interview with the LD on 10/5/2022 at 9:00 AM confirmed the LD did not have a lab manual for the location. 3. The laboratory performs 300 compliance level tests per year under the specialty of Pathology.