

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2007508	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier New England Cryogenic Center, Inc	Street Address, City, State 500 Donald J Lynch Blvd, Marlborough, MA	
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
D0000	A CLIA recertification survey was conducted for the New England Cryogenic Center, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory did not have a written competency procedure which includes direct observation of testing personnel. A review of the Standard Operating Procedures manual revealed that the laboratory did not have a written competency procedure. The technical supervisor confirmed this on 12/11/18 at 10:38 AM. The laboratory performs approximately 10,000 bacteriology and mycology screens annually.</p>
D6121	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the technical supervisor failed to include direct observation when performing competency assessments of testing personnel. A review</p>

of personnel records for four of four testing personnel performing and/or supervising laboratory testing revealed the fact that there was only a written test assessed for both six month and annual competencies. No direct observation of laboratory personnel performing testing was including in the competency assessment. The technical supervisor confirmed this on 12/11/18 at 10:38 AM. The laboratory performs approximately 10,000 bacteriology and mycology screens annually.