

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2007508	(X3) Date Survey Completed 04/01/2021
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. Due to the nature of the deficiencies cited herein, the following Condition level deficiency was deemed to be not met: 42 CFR 493.801- Condition: Enrollment and Testing of Samples (Proficiency Testing). .
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with laboratory personnel on 4/1/21, it was determined that the New England Cryogenic Center, Inc. laboratory referred proficiency testing samples to another laboratory during calendar years 2018, 2019 and 2020. A total of six (6) samples were referred to the other off site laboratory. Cross Reference D2013 Standard: Enrollment and testing of samples. .</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency</p>

testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on policy and record review of the College of American Pathologists (CAP) proficiency testing records and confirmed through an interview on 4/1/21 with the Technical Supervisor for Bacteriology and Mycology and the Laboratory Director the laboratory failed to ensure that proficiency testing samples were not sent to another laboratory as evidenced by the following: a) A review of proficiency testing results during a CLIA recertification surveys on 4/1/21 revealed that the laboratory sent out proficiency testing samples to a reference laboratory in Centennial Colorado (CLIA ID 06D0717586) for positive proficiency testing cord blood cultures for calendar years 2018, 2019 and 2020 b) The Technical Supervisor for Bacteriology and Mycology stated in an interview on 4/1/21 at 9:20 AM that the laboratory was following it's standard policy of sending out all positive cord blood cultures to the reference laboratory for identification. She was unaware that proficiency testing samples were not to be sent out to another laboratory and initially stated that the samples were sent to the reference laboratory after the proficiency testing results had been submitted to CAP as they only perform screens for positive or negative growth. However in an email received on 4/2/21 at 10:55 am she indicated that the laboratory ships out the positive bottles immediately for testing in line with the current lab SOPS, therefore the results from the reference laboratory is received prior to the CAP submission of results. c) Review of the laboratory's standard operating procedure, "Shipping Out Positive Bactec Bottles for Identification", confirmed that all positive cord blood cultures are sent to a reference laboratory for organism identification. d) A total of six (6) samples were referred to the reference laboratory between calendar years 2018 and 2020. .

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview, the laboratory director failed to ensure the proficiency testing samples were tested as required under subpart H of this part as evidenced by the following: a) Review of proficiency testing records and interview with the Technical Supervisor on 4/1/21 at 9:20 a.m. confirmed that the

laboratory referred proficiency testing samples for positive cord blood cultures to a reference laboratory and received the results back prior to submitting results to the College of American Pathologists (CAP) proficiency testing program. b) A total of six (6) samples were referred to the reference laboratory between calendar years 2018 and 2020. Cross Reference D2013 Standard: Enrollment and testing of samples.