

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0702012	(X3) Date Survey Completed 01/29/2019
Name of Provider or Supplier Trinity Health Of New England Medical Group	Street Address, City, State 1515 Allen St, Springfield, 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 Family Care Medical Center laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to correct problems identified when proficiency testing results were found to be unacceptable as evidenced by the following: a) A review of proficiency testing for calendar years 2017 and 2018 revealed that the laboratory received unacceptable scores for Toxicology, Bacteriology and Routine Chemistry for 2018 (Testing event 1-Buprenorphine 67%; Testing event 2 - waived strep 50%; and, testing event 3 - Sodium and Chloride 60%). b) In each case the root of the problem was identified as a transcription error. c) In each case there was no remedial action documented to ensure that transcription errors for proficiency testing result submittal would not recur. d) The technical consultant and laboratory technologist confirmed in an interview on 1/29/19 at 2:00 PM that no remedial action to correct the problem of transcription errors had been undertaken. .</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant failed to evaluate and document the performance of all individuals responsible for moderate complexity testing at least annually as evidenced by the following: a) Findings revealed that the technical consultant failed to evaluate the competency, at least annually, of one (1) out of seven (7) laboratory technologists for calendar year 2018. b) This was confirmed through an interview with the technical consultant on 1/29/19 at 9:15 AM.