

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0908249	(X3) Date Survey Completed 08/06/2019
Name of Provider or Supplier Children's Health Care	Street Address, City, State 600 Primrose Street Ste 200, Haverhill, 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 Children's Healthcare laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the medical assistant, the laboratory failed to ensure the test report indicated the correct location site where the test was performed as evidenced by the following: The surveyor reviewed ten patient records from January 2018 through July 2019 in the laboratory's Electronic Medical Record (EMR), eClinicalWorks. The review revealed that the laboratory failed to indicate the correct name and address of the laboratory location where the test was performed for two (2) out of ten (10) reports. The test was performed at the practice's Newburyport location and this location was not indicated on the final test report. The medical assistant confirmed on 8/6/19 at 12:05 PM that the laboratory failed to indicate the correct name and address of the laboratory location where the test was performed. The laboratory performs 617 throat cultures annually.</p>
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview, the technical consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor reviewed the personnel competency records for calendar years 2018 and 2019. The review revealed that semiannual competency evaluations were not performed and documented for two (2) out of two (2) newly hired testing persons (TP) for calendar year 2018. The medical assistant confirmed in an interview on 8/6/19 at 10:35 A.M. that the TC failed to perform and document semiannual competency evaluations for the two new TP.