

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0081808	(X3) Date Survey Completed 03/22/2019
Name of Provider or Supplier Pediatric Associates Of New Bedford	Street Address, City, State 225 Field Street, New Bedford, 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 Pediatrics Associates of New Bedford 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, the laboratory failed to indicate on the final patient test report the name and address of the referring laboratory where the test was performed as evidenced by the following: Surveyors reviewed fourteen (14) final patient test reports between 11/30/17 and 3/18/19 in the Epic Electronic Medical Record (EMR). The review revealed the name of the referring laboratory on the final patient test reports in the Epic EMR was Southcoast. The referring laboratory's name and address is St Luke's Hospital, 101 Page Street, New Bedford, MA 02740. The laboratory transitioned EMR vendors from eClinical Works to Epic in 2017. The technical consultant and testing person 1 confirmed in an interview on 3/22/19 at 3:00 P.M. that the final patient test reports did not indicate the name and address of the referring laboratory where the test was performed.</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: Surveyors reviewed the personnel competency records for calendar years 2017 and 2018 on 3/22/19. The review revealed that semiannual competency evaluations were not performed and documented for three (3) out of three (3) newly hired testing persons (TP) for calendar year 2018. The TC and TP1 confirmed in an interview on 3/22/19 at 10:08 A.M. that the TC failed to perform and document semiannual competency evaluations for the three new TP.