

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0073656	(X3) Date Survey Completed 04/09/2019
Name of Provider or Supplier North Shore Physicians Group Urology	Street Address, City, State 400 Highland Ave, Salem, 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 Urology Consultants of the North Shore 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 laboratory where the test was performed as evidenced by the following: 1. The laboratory refers the technical component of Histopathology and Cytology tests to North Shore Medical Center Salem. Surveyors reviewed ten (10) final Pathology patient test reports generated in the Pathology Copath software between 10/26/17 and 2/26/19 on 4/9/19. The review revealed the name of the laboratory performing the technical component was "NSMC Labs." The practice manager confirmed in an interview on 4/9/19 at 11:32 A.M. that the final patient test reports did not indicate the name of the laboratory where the test was performed. The laboratory performs 6,293 Pathology slide examinations annually. 2. The laboratory implemented the Epic Electronic Medical Record (EMR) in October of 2017. Surveyors reviewed six (6) final urine culture screen patient test reports between 2/8/18 and 2/13/19 in the EMR on 4/9/19. The review revealed the</p>

name of the the laboratory in the EMR was "NSC URO CONS SALEM" and there was no address of the laboratory location where the test was performed. The laboratory's name and address is Urology Consultants of the North Shore, 400 Highland Avenue, Salem, MA 01970. The practice manager and testing person 1 confirmed in an interview on 4/9/19 at 12:05 P.M. that the final patient test reports did not indicate the name and address of the laboratory where the test was performed. The laboratory performs 7,402 urine cultures screens annually.

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 personnel competency records for calendar years 2017 and 2018 on 4/9/19. The review revealed that semiannual competency evaluations were not performed and documented for one (1) newly hired testing person (TP) performing moderate complexity testing for calendar year 2018. The practice manager confirmed in an interview on 4/9/19 at 9:15 A.M. that the TC failed to perform and document semiannual competency evaluations for the new TP.