

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2179021	(X3) Date Survey Completed 02/28/2024
Name of Provider or Supplier Comprehensive Urology Institute, Inc	Street Address, City, State 3660 Stutz Drive, Suite 202, Canfield, OH	
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
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 an interview with the Laboratory Director, the laboratory failed to indicate the address of the laboratory location where the tissue biopsy and cytology slide interpretations were performed on the final test reports. This deficient practice had the potential to affect 5,000 out of 5,000 patient tissue biopsy and cytology slide interpretations performed in the specialty of Pathology between the last CLIA inspection on 03/02/2022 and 02/28/2024. Findings Include: 1. Review of 10 out of 10 of the laboratory's 2023 and 2024 patient final test reports provided for the inspection, did not find the address of the laboratory location where the professional component of tissue biopsy and cytology slide interpretations were performed. 2. The Laboratory Director confirmed on 02/28/2024 at 9:23 AM, that the patients final test reports did not contain the laboratory's address of where the tissue biopsy and cytology slide interpretations were performed.</p>