

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2286784	(X3) Date Survey Completed 01/09/2024
Name of Provider or Supplier Souza Pathology	Street Address, City, State 335 S Main St, Chatham, VA	
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	An announced CLIA initial survey was conducted at Souza Pathology on January 8, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included an offsite follow up interview with the lab director on 1/9 /24. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
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 a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) Aspen database and CMS survey 116 form, patient test logs, lack of documentation, and interviews, the laboratory failed to ensure that surgical tissue pathology test reports included the correct performing laboratory name and address for two hundred seven (207) of 207 patient reports as noted during the initial survey on January 8, 2024. Findings include: 1. During pre-survey inspection duties, the inspector noted that the CMS Aspen database listed the laboratory's name and physical facility location as: Souza Pathology (CLIA ID 49D2286784) 335 S. Main Street Chatham, Virginia 24531 Review of the laboratory's submitted CMS 116 form confirmed the above name and address. 2. Review of the laboratory patient test logs revealed 207 histopathology cases. The inspector requested to review the following</p>

nine randomly selected pathology test results (accession/case numbers) from the test logs: 2024004Q860508, 2024002Q860505, 2024004Q860507, 2024004Q860512, 2024004Q860505, 2024004Q860503, 2024004Q860504, 2024004Q860513, and 2024004Q860501. The inspector's review revealed that the selected patient reports failed to identify the correct performing laboratory name/physical location of the surgical histopathology microscopy evaluation. The inspector noted the report included a footnote "performing labs" with the following information: Laboratory Corporation of America Holdings Component Type - Technical, Professional TW Alexander Drive, Research Triangle Park, NC 27709 CLIA 34D0655205 3. The inspector inquired regarding the performing laboratory footnote outlined above. The laboratory director (LD) confirmed on 1/8/24 at approximately 2:30 PM that all 207 patient case reports (to date) failed to correctly identify the pathology component's performing laboratory name/physical location. 4. A offsite follow up interview with the LD on 1/9/24 at approximately 3:30 PM confirmed the above findings.