Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2286784	07/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Souza Pathology	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 recertification survey was conducted at Souza Pathology on July 10, 2025 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 7/11/25. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of procedures, proficiency testing logs, lack of documentation, and interviews, the laboratory failed to perform surgical tissue pathology/histology accuracy checks by peer review twice annually per laboratory policy during calendar year 2024 and up to the date of the recertification inspection (review timeframe: January 10, 2024 to July 10, 2025). Findings include: 1. Review of the laboratory's procedure manual revealed a policy for proficiency testing of surgical surgery histology specimens ("Quality Assurance Peer Review"). The written policy stated "the laboratory will pull random cases (30-50) twice per year for peer review." 2. Review of the laboratory's peer review documentation for calendar year 2024 up to the date of survey on 7/10/25 revealed documentation that surgical pathology tissue split sample testing (forty-five cases) were sent out for peer review on 12/9/24. The inspector requested to review additional peer review that was performed in 2024 and year to date 2025. No additional documentation of peer review was available. 3. The inspector inquired as to the reason peer review cases were not pulled twice annually as outlined in the quality assurance policy. The laboratory director (LD) stated on 7/10 /25 at 4:30 PM, "I realized last week preparing for this CLIA visit that cases were not pulled twice annually. I have scheduled the peer review immediately to validate the

	original diagnosis and to comply with CLIA for proficiency standard". 4. An offsite exit interview with the LD on 7/11/25 at 10 AM confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), policies, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director (LD) failed to identify quality assessment failures as they occurred for two of three peer review assessments missed during the recertification review (timeframe: 1/10/24 - 7/11/25). *Refer to D5217. Findings include: 1. Review of the CMS 116 report revealed that the LD identified high complexity patient Surgical Pathology Level IV histopathology slide reading with special and immunohistochemical stains performed during the review timeframe of 1/10/24 - 7/11/25. 2. Review of procedures revealed a PT policy for surgical surgery histology specimens slide reading ("Quality Assurance Peer Review"). The policy stated "the laboratory will pull random cases (30-50) twice per year for peer review." 3. Review of the laboratory's PT documentation for calendar year 2024 up to the date of survey on 7/10/25 revealed one event of peer review (dated 12/9/24). The inspector requested to review additional peer review records. No additional documentation for expected peer review performed in June 2024 and June 2025 were available. 4. The inspector inquired regarding records that documented the identification/corrective action for the failures to adhere to the LD approved "Quality Assurance Peer Review" policy for the timeframe outlined above. No corrective action documentation was available for review. 5. An offsite exit interview with the LD on 7/11/25 at 10 AM confirmed the above findings.