Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2213816	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Surgery Center Of Southwest Ohio, Llc, The	2210 Arbor Blvd, Ste 1a, Moraine, 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
D0000	Based on record review and an interview with the Administrator, the Laboratory Director (LD) failed to ensure compliance with the regulations when proof of accreditation was not obtained within the 11 months of application in accordance with Code of Federal Regulations (CFR) 493.57. This deficient practice had the potential to affect 26 out of 26 patients tested in the subspecialty of Histopathology. Findings include: 1. Review of the CMS - 116 application dated and signed by the laboratory director on 06/17/24 revealed the laboratory requested to change from a Certificate of Waiver to a Certificate of Accreditation. The laboratory received a Certificate of Registration until accreditation. 2. During a phone interview with the Administrator on 03/12/2026 at 8:18 AM, the Administrator stated the laboratory had not submitted the Accreditation Commission for Health Care application for accreditation. 3. Review of CFR 493.57 Requirements for a registration certificate states A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS. (a) HHS will issue a registration certificate if the laboratory- (1) Complies with the requirements of 493.55; (2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only); (3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and (4) Remits the fee for the registration certificate specified in subpart F of this part. (b) (1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program- (i) Within 11 months of issuance of the registration certificate; or (ii) Prior to the expiration of the certificate of compliance. (2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of 493.49.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) 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. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Clinical Director (CD), the laboratory failed to include the correct name and address where the frozen tissue biopsy tests were performed, on 19 out of 19 patient test reports reviewed. This deficient practice affected 19 patient test reports of 26 total patients tested from 08/12 /2024 through 12/04/2025, in the subspecialty of Oral Pathology. Findings Include: 1. Review of 19 patient frozen tissue surgical pathology reports, dated from 02/13/2025 through 12/04/2025, found 580 Lincoln Park Blvd., Suite 344, Kettering, Ohio 45429 listed as the frozen tissue surgical laboratory testing address. The frozen tissue surgical testing laboratory physical address is 2210 Arbor Blvd, Suite 1A, Moraine, Ohio 45439. 2. On 03/03/2026 at 3:30 PM the CD stated that the address listed on the test report was the Laboratory Director's other office location and not the surgical center address where the frozen tissue biopsies and reports are performed. The CD confirmed the address on the frozen tissue biopsy test reports was incorrect.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review, policy and procedure review, and interviews with the Administrator and Clinical Director, the Laboratory Director (LD) failed to be responsible for the overall operation and administration of the laboratory including ensuring compliance with applicable regulations and obtaining proof of accreditation within the 11 months of application in accordance with Code of Federal Regualtions (CFR) 493.57. This deficient practice had the potential to affect 26 out of 26 patients tested in the subspecialty of Histopathology. Findings include: 1. The LD failed to enusre compliance with the regulations when proof of accreditation was not obtained within the 11 months of application in accordance with Code of Federal Regulations (CFR) 493.57. (Refer to D000) 2. The LD failed to ensure verification procedures were used to determine the accuracy, precision, and other pertinent performance characteristics for the high complexity frozen tissue diagnostic slide interpretations performed. (Refer to D6086) 3. The LD failed to ensure that the quality control and quality assessment programs were established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur. (Refer to D6093) 4. The LD failed to ensure an approved procedure manual is available to all personnel responsible for any aspect of the testing process. (Refer to D6106)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy,

	precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and an interview with the Administrator, the Laboratory Director failed to ensure verification procedures were used to determine the accuracy, precision, and other pertinent performance characteristics for the high complexity frozen tissue diagnostic slide interpretations performed in 2024 and 2025. This deficient practice had the potential to affect 26 out of 26 patients tested in the subspecialty of Oral Pathology from 08/12/2024 through 12/04/2025. Findings Include: 1. Review of the patient logs titled "Frozen Log - Surgery Center of Southwest Ohio" provided on the day of inspection found 26 patients listed for frozen tissue biopsies from 08/12/2024 through 12/04/2025. No patients had been tested through the date of inspection in 2026. 2. Review of the requested laboratory's policies and procedures provided via email by the Administrator on 03/11/2026, did not find any mention of blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity frozen tissue diagnostic slide interpretations performed in 2024 and 2025. 3. During a phone interview on 03/12/2026 at 8:18 AM with the Administrator, the Inspector requested the blind TAV activities, at least twice annually, for the high complexity frozen tissue diagnostic slide interpretations performed in 2024 and 2025. The Administrator stated all available policies and procedures have been transmitted via email, and verified the provided documentation represents the complete and total set of facility policy and protocols, and was unable to provide the requested information.
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 record review, direct observation, and interviews with the Administrator and the Clinical Director (CD), the Laboratory Director failed to ensure that the quality control and quality assessment programs were established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur. This deficient practice had the potential to affect 26 out of 26 patients tested in the subspecialty of Oral Pathology from 08/12/2024 through 12/04/2025. Findings Include: 1. Review of the patient logs titled "Frozen Log - Surgery Center of Southwest Ohio" provided on the day of inspection found 26 patients listed for frozen tissue biopsies from 08/12/2024 through 12/04/2025. No patients had been tested through the date of inspection in 2026. 2. Direct observation of the laboratory on 03/03 /2026 at 2:20 PM did not find any quality control documentation. The inspector requested quality control documents from the CD during the laboratory observation and the CD stated she was unaware of quality control performed for the frozen tissue stains conducted in 2024 through 2025. 3. Review of the requested laboratory's policies and procedures provided via email by the Administrator on 03/11/2026, did not find any mention of quality control and quality assessment programs to assure the quality of laboratory services provided, and to identify failures in quality as they occur. 4. During a phone interview with the Administrator on 03/12/2026 at 8:18 AM, the Inspector requested policies and procedures and documentation of all quality

	control and quality assessment programs to assure the quality of laboratory services provided, and to identify failures in quality as they occur. The Administrator stated all available policies and procedures have been transmitted via email, and verified the provided documentation represents the complete and total set of facility policy and protocols, and was unable to provide the requested information.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on record review and an interview with the Administrator, the Laboratory Director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This deficient practice had the potential to affect 26 patients, which included 40 patient slides from the 26 patients, tested in the subspecialty of Oral Pathology from 08/12/2024 through 12/04 /2025. Findings Include: 1. Review of the patient logs titled "Frozen Log - Surgery Center of Southwest Ohio" provided on the day of inspection found 40 patient slides listed for frozen tissue biopsies from 08/12/2024 through 12/04/2025. No patients had been tested through the date of inspection in 2026. 2. Review of the requested laboratory's policies and procedures provided via email by the Administrator on 03/11 /2026, did not find any mention of procedures for the preparation of slides and controls used in testing, control procedures, and corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. 3. During a phone interview on 03/12/2026 at 8:18 AM, the Inspector requested procedures for the preparation of slides and controls used in testing, control procedures, and corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. The Administrator stated all available policies and procedures have been transmitted via email, and verified the provided documentation represents the complete and total set of facility policy and protocols, and was unable to provide the requested information.