Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1037323	05/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dearborn Surgery Center	18100 Oakwood Blvd Suite 100, Dearborn, MI	

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 recertification survey was performed on May 19, 2025 at Dearborn Surgery Center by the State of Michigan Licensing and Regulatory Affairs Department. During the survey, it was determined Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: 493.1219 Condition: Histopathology. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation and interviews with the administrator and the laboratory director, the laboratory failed to establish written policies to ensure positive identification of its patient histopathology slides (refer to D5203), failed to establish test procedures for its frozen section histopathology testing to include the preparation of slides, performance of gross tissue examinations, and microscopic tissue examinations (refer to D5403), and failed to ensure quality control programs were established to include predictable staining characteristics for its hematoxylin and eosin staining materials at least each day of patient testing (refer to D5473).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: . Based on observation and interviews with the administrator and the laboratory director, the laboratory failed to establish written policies to ensure positive identification of its patient histopathology slides for 9 (patients) of 11 patient cases performed between 6/9/23 to 5/19/25. Findings include: 1. A review of the laboratory's test volume revealed the laboratory performed histopathology frozen sections for 11 patients between 6/9/23 to 5/19/25. Nine of the 11 patient cases had slides available for review. The slides included patient identification stickers with the name of another laboratory, laboratory B under a different CLIA certificate. These stickers overlapped the coverslip on some of the slides, showing they were added after the specimen slides were prepared. The surveyor peeled back and held the slides to the light to see what the labeling was underneath the stickers to reveal the following information: a. Patient #1, with testing performed on 6/28/23, had 10 slides prepared and read at this laboratory: i. Two slides did not include any labeling. ii. Eight slides included the case number and letters denoting the sections, "B1-1", "B1-2", "C1-1", C1-2", "D1-1", "D1-2", "E1-1", and "E1-2". iii. No name was included on the slides. b. Patient #3, with testing performed on 1/10/24, had seven slides prepared and read at this laboratory: i. Two slides did not include any labeling. ii. Five slides included letters and numbers denoting the sections, "A2-1", "A2-2", "A3-1", "A3-2", and "A3-3". iii. No name or case number was included. c. Patient #4, with testing performed on 6/13/24, had six slides prepared and read at this laboratory: i. All six slides included letters and numbers denoting the sections, "A1/1", "A1/2", "B1/1", "B1/2", "C1/1" and "C1/2". ii. No name or case number was included. d. Patient #6, with testing performed on 7/6/23, had six slides prepared and read at this laboratory: i. Two slides did not include any labeling. ii. Four slides included the case number and letters denoting the sections "B1-1", "B1-2", "C1-1", and "C1-2". iii. No name was included. e. Patient #7, with testing performed on 6/9/23, had six slides prepared and read at this laboratory: i. Two slides did not include any labeling. ii. Four slides included the letters denoting the sections "A2-1", "A2-2", "A3-1", and "A3-2". iii. No name or case number was included. f. Patient #9, with testing performed on 2/23/24, had four slides prepared and read at this laboratory: i. Two slides did not include any labeling. ii. Two slides included the numbers denoting the sections "1-3" and 1-4". iii. No name or case number was included. g. Patient #10, with testing performed on 11/22/23, had 12 slides prepared and read at this laboratory: i. Six slides did not include any labeling. ii. Six slides included the letters denoting the sections "A3 11", "A3 12", "A4 11", "A4 12", "C 11", and "C 12". iii. No name or case number was included. h. Patient #11, with testing performed on 8/25/23, had six slides prepared and read at this laboratory: i. All six slides include the letters denoting the sections "A1-1", A1-2", "B1", "B12", "C1.1", and "C1.2". No name or case number was included. i. Patient #12, with testing performed on 10/12/23, had four slides prepared and read at this laboratory: i. Three slides included a last name and first initial with "B12", "BLL", and "F212A". No full name or case number included. ii. One slide included "F211 A" without a name or case number. 2. A review of the laboratory's "Specimen collection- Care, Handling, and Disposal" procedure revealed a lack of specimen labeling policy. 3. An interview on 5/19/25 at 2:04 pm with the administrator and the laboratory director confirmed the slides listed above were not labeled to ensure positive patient identification while the specimens were at the laboratory. The stickers on the slides were generated after the frozen section histopathology testing at the laboratory was completed and sent to reference laboratory for additional testing.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on record review and interviews with the administrator and laboratory director, the laboratory failed to establish test procedures for its frozen section histopathology testing to include the preparation of slides, performance of gross tissue examinations, and microscopic tissue examinations for two (May 2023 to May 2025) of two years reviewed. Findings include: 1. A review of the laboratory's test procedures revealed a lack of procedures for how the laboratory performs gross tissue examinations, prepares tissue slides, and performs microscopic tissue examinations. 2. On 5/19/25 at 1:49 pm, the administrator provided a paper that was taped to the wall in the laboratory titled "[name redacted] Histology Procedure Frozen Section Hematoxylin and Eosin Rapid Staining Procedure", which was provided by another laboratory and did not include approval from the laboratory director for this laboratory. 3. An interview on 5/19/25 at 1:49 pm with the laboratory director confirmed the laboratory's test procedures did not include how the laboratory performs gross tissue examinations, prepares tissue slides, and performs microscopic tissue examinations for its frozen section histopathology testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: . Based on record review and interview with the administrator and laboratory director, the laboratory failed to ensure quality control programs were established to include predictable staining characteristics for its hematoxylin and eosin staining materials at least each day of patient testing for 11 (6/9/23, 6/28/23, 7/6/23, 7/10/23, 8/25/23, 8/31/23, 10/12/23, 11/22/23, 1/10/24, 2/23/24, and 6/13/24) of 11 total patient testing dates

	between 6/9/23 and 5/19/25. Findings include: 1. A review of the laboratory's list of patients receiving frozen section histopathology testing from 6/9/23 and 5/19/25 revealed staining with its hematoxylin and eosin staining materials was performed on: a. 6/9/23 b. 6/28/23 c. 7/6/23 d. 7/10/23 e. 8/25/23 f. 8/31/23 g. 10/12/23 h. 11/22/23 i. 1/10/24 j. 2/23/24 k. 6/13/24 2. The surveyor requested the laboratory's documentation of stain quality for the patient testing dates listed above on 5/19/25 at 1: 59 pm and it was not made available. 3. An interview on 5/19/25 at 1:59 pm with the administrator confirmed documentation of stain quality for the patient testing dates listed above was not present.
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 observation, record review, and interviews with the administrator and laboratory director, the laboratory director failed to ensure written policies for positive identification of its patient histopathology slides were established (refer to D6082), failed to ensure quality control programs were established to include predictable staining characteristics for its hematoxylin and eosin staining materials at least each day of patient testing (refer to D6093), and failed to establish test procedures for its frozen section histopathology testing to include the preparation of slides, performance of gross tissue examinations, and microscopic tissue examinations (refer to D6106).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: . Based on observation and interviews with the administrator and the laboratory director, the laboratory director failed to ensure written policies for positive identification of its patient histopathology slides were established. Refer to D5203.
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 and interview with the administrator and laboratory director, the laboratory director failed to ensure quality control programs were established to

	include predictable staining characteristics for its hematoxylin and eosin staining materials at least each day of patient testing. Refer to D5473.
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 interview with the administrator and laboratory director, the laboratory director failed to establish test procedures for its frozen section histopathology testing to include the preparation of slides, performance of gross tissue examinations, and microscopic tissue examinations. Refer to D5403.