

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2329297	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Spartan Genetix Llc	Street Address, City, State 47951 Ann Arbor Road, Plymouth, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) (a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory director, the laboratory failed to retain histopathology slides for 6 (P2, P4, P5, P8, P9, and P10) of 10 patients reviewed. Findings include: 1. On 03/04/2026 at 9:30 am, the surveyor requested 10 patient histopathology slides for review. The following patient slides were not provided: a. P2 - slide examination performed on 10/03/2025 b. P4 - slide examination performed on 11/11/2025 c. P5 - slide examination performed on 12/02/2025 d. P8 - slide examination performed on 01/09/2026 e. P9 - slide examination performed on 02/16/2026 f. P10 - slide examination performed on 02/16/2026 2. On 03/04/2026 at 11:36 am, an interview with the laboratory director confirmed that 6 of the 10 requested histopathology slides were not available for review.
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 review and interview with the laboratory director (LD), the laboratory failed to ensure that the name and address of the laboratory performing the histopathology slide examinations were included on the test reports for 10 (P1-P10) of 10 patients reviewed. Findings include: 1. On 03/04/2026 at 9:30 am, the surveyor requested 10 patient test reports for review. 2. A review of 10 patients (P1 - P10) test reports revealed the reports did not include the name and address of the laboratory performing the histopathology slide examination, as follows: a. P1 - slide examination performed on 10/13/2025 b. P2 - slide examination performed on 10/03/2025 c. P3 - slide examination performed on 11/06/2025 d. P4 - slide examination performed on 11/11/2025 e. P5 - slide examination performed on 12/02/2025 f. P6 - slide examination performed on 12/29/2025 g. P7 - slide examination performed on 01/09/2026 h. P8 - slide examination performed on 01/09/2026 i. P9 - slide examination performed on 02/16/2026 j. P10 - slide examination performed on 02/16/2026 3. On 03/04/2026 at 11:06 am, an interview with the LD revealed that the the laboratory receives histopathology slides from a referring laboratory for review and interpretation. Following interpretation, the results are communicated to the referring laboratory. The referring laboratory generates the test report and lists their name and address on the test report. The laboratory director confirmed the name and address of the laboratory performing the histopathology slide examination was not listed on patient test reports.