Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2299423	03/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Naperville Pathology	1120 Cordula Circle, Naperville, IL	

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
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 laboratory policies and procedures, review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to perform bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) at least twice annually for histopathology testing in the year of 2024. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Slide Consultation", which stated, under "Peer Review:", "1. Twice per year, the [Premier Medical Group] PMG pathologist will select 2-4 cases for a second opinion to a pathologist of PMG's choice. 2. Review of laboratory records, including that of bi-annual peer reviewed histopathology interpretations, revealed only one peer reviewed histopathology case was sent out in the year of 2024. Date: Case #: 02/05/2024 S24-00271 3. Interview with the LD on 03/10/2025, at 11: 48 am, confirmed the laboratory failed to perform bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) at least twice annually for histopathology testing.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of

	documentation, and interview with the laboratory director (LD), the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) from the beginning of testing, December 2023, to the date of survey, 03/10/2025, in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure, "Slide Consultation", which stated, under "Peer Review:", " ...2. Slides sent out will be documentation in the Case Send Out Log. The patient's name, date, results, and the second pathologist' results will be documented by the PMG pathologist." 2. Review of laboratory records revealed a lack of documentation of evaluations of results upon receipt of peer reviewed histopathology interpretations for one of one applicable reviewed bi-annual method accuracy events (see D5217). 3. Interview with the LD on 03/10/2025, at 11:48 am, confirmed the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed histopathology interpretations) from the beginning of testing, December 2023, to the date of survey, 03/10/2025, in the subspecialty of histopathology.
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 review of patient test reports, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to ensure patient test reports included all required information for five of five patient test reports reviewed from the beginning of testing, December 2023, through the date of survey, 03/10/2025, in the subspecialty of histopathology. Findings include: 1. Review of patient test reports for histopathology testing failed to indicate the address of the laboratory location where the test was performed for five of five test reports reviewed. Date: Case Number: 12 /18/2023 S23-03011 03/22/2024 S24-00669 06/10/2024 P24-00173 10/31/2024 S24-02597 02/19/2025 S25-00365 2. Interview with the LD on 03/10/2025, at 12:11 pm, confirmed the laboratory failed to ensure patient test reports included all required information for five of five patient test reports in the subspecialty of histopathology.