Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2227207	11/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory & Pathology Diagnostics	1220 Hobson Rd - Ste 244, 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
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 review of the laboratory's policy and procedure manual, lack of documentation and interview with Testing Personnel (TP) #2; the laboratory failed to outline all required components of the test procedure for Immunohistochemistry (IHC) staining. Findings include: 1. Review of the laboratory's policy and procedure manual for immunohistochemistry (IHC) staining under the section titled "Results

	Reporting" revealed that the laboratory failed to have control procedures for IHC staining. 2. On survey date 11/19/2025, at 12:20 pm, TP #2 confirmed that the laboratory failed to have quality control procedures in place for IHC staining.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain 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 Testing Personnel (TP) #2, the laboratory failed to check and document immunohistochemical (IHC) stains for positive and negative reactivity for two of two patient IHC testing dates reviewed. Findings include: 1. Review of laboratory policies and procedures revealed the laboratory failed to have Quality control procedures in place for IHC staining. See D5403. 2. Review of patient testing results for two of two IHC stain testing dates found that positive and negative reactivity was not documented for IHC staining. Report Date: MRN: 10/06/2025 GE11218065 08/18/2023 GE11308079 3. Interview with TP #2 on 11/19/2025, at 12: 20 pm, confirmed the laboratory failed to document IHC stain QC for positive and negative reactivity.