Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1101789	10/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ameripath Milwaukee Sc Dba Ameripath Great Lakes	506 East State Parkway, Suite A, Schaumburg, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedures manual and quality control records, the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283. Findings: 1. There was no comprehensive procedures manual that described the laboratory's preanalytical, analytic and post analytic processes. See D tag 5403 2. There was no quality control procedures that include the following: o Type of control (e.g., manufacturer or in-house, electronic); o Identity (e.g., normal, abnormal, level I, II, patient or a control); o Number and frequency of testing controls; o Control limits established in accordance with 493.1253 and 493.1256; and o Criteria to determine acceptable control results. See D tag 5601.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 observations, interview with the laboratory director and review of procedures manuals; the laboratory failed to have a comprehensive procedures manual for histopathology and cytology tests it performed. Findings: 1. Review of the laboratory's procedure manual revealed that the laboratory used Quest Diagnostics Laboratory's electronic procedures as part of its procedure's manual. 2. The procedure manual did not include applicable procedures pertaining to this laboratory as listed below. a. 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. Microscopic examination, including the detection of inadequately prepared slides. c. Step-by-step performance of the procedure, including test calculations and interpretation of results. d. Control procedures. e. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. f. Imminently life-threatening test results, or panic or alert values. g. 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. h. Description of the course of action to take if a test system becomes inoperable 3. During survey date October 9, 2019 at 4:00 PM, the laboratory director confirmed the surveyor's findings.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of procedures manuals, patients' test reports, quality control records and interview with the laboratory director; the laboratory failed to perform and document the quality of its immunohistochemical stains and and differential stains. Findings 1. There were no procedures that described the laboratory's process for the performance and documentation of quality control of each staining process. 2. Existing Quality control documents listed the Site location as Quest Diagnostics and

	Ameripath Great Lakes. The surveyor could not determine for which lab the laboratory director performed quality controls. 3. There were no reactions of the control stains documented with each special stain. 4. During survey date October 9, 2019, at 4:00 PM the laboratory director confirmed the surveyor's findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of quality control records and interview with the laboratory director; the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. There were no procedures that described the laboratory's process for performing and documenting special stains, immunohistochemical stains, and differential stains. See D tag 5601 2. During survey date on October 2019, 4:00 PM the laboratory director confirmed the surveyor's findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with the laboratory director, the laboratory director failed to ensure that an approved procedure manual is available for all aspects of testing this laboratory performs. Findings: 1. Review of the laboratory's procedure manual revealed that the laboratory used Quest Diagnostics Laboratory's electronic procedures as part of its procedure's manual. The procedures manual contained procedures that this laboratory does not perform. 2. During survey date on October 9, 2019, at 4:00 PM the laboratory director confirmed the surveyor's findings.