Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2119652	02/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
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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) 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 review of the procedure manual and interview with laboratory director (LD), the laboratory did not provide the testing personnel with written procedures for distribution of the final report and storage of the requisitions, reports, and any other laboratory records. Findings: 1. During the survey the LD stated that once the final interpretations are entered into the electronic medical record two copies of the final report are printed and distributed. Review of the procedure manual showed that there were no written policies and procedures for the distribution of the two final reports. 2. During the survey the LD stated that some of the laboratory records are stored at the

	office and others are stored at the staining laboratory. Review of the procedure manual showed that the "Record Retention" section did not identify whether the records were stored at the laboratory or at the staining laboratory. 3. During the survey on 02/21/18 at 12:15 PM the LD confirmed that the policy and procedure manual did not include the procedures for the distribution of the two final reports and where different records were stored.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) worksheets and interview with the laboratory director (LD), the histopathology laboratory did not document that it checked the Hematoxylin and Eosin (H&E) stain and special stains for intended response, and predicted characteristics of the stain. Findings: 1. The LD is the testing person for four laboratories which share the same space, electronic medical records and microscope. 2. The QC worksheets for January and February 2018 were reviewed and did not identify that QC was performed on the H&E and special stains for each of the four laboratories each day of testing. 3. During the survey on 02/21/18 at 12:15 PM the LD confirmed that the QC worksheets did not identify the documentation of the QC for each of the four laboratories independent of each other.
D5805	TEST REPORT CFR(s): 493.1291(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 patients' final reports in the electronic medical report (EMR) and interview with the laboratory director, the laboratory did not ensure that the final test report listed the name of the laboratory performing the final interpretations. Findings: 1. During the survey two patient charts were pulled to review the final report with the patients' final interpretations. Two of the two that were reviewed did not include the name of the laboratory performing the final interpretations. 2. During the exit interview on 02/21/18 at 12:15 PM the laboratory director confirmed that the final reports in the EMR did not include the name of the laboratory performing the final interpretations.