Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2119152	07/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dupage Medical Group-Hoffman Estates 1	2359 Hassell Rd, Hoffman Estates, 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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, review, and interview; the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299. Findings: 1. Review of laboratory records revealed the following: a. There was no documentation to show that the laboratory verified the accuracy of its histopathology procedures. See D tag 5217. b. There was no documenation to show that tests were actually ordered. See D tag 5305. 2. The laboratory lacked a comprehensive procedures manual that has all required information. See D tags 5403, 5407, and 5409. 3. Test reports did not include the laboratory location where all tests are performed. See D tag 5805
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 and interview; the laboratory failed to verify the accuracy of its histopathology procedures. Findings: 1. Review of laboratory policies and procedures revealed that there were no procedures that describes how the laboratory verifies the accuracy of it histopathology procedures. 2. There was no documentation to show that

	the laboratory verified its histopathology procedures from June 2017 through July 2018. 3. During survey date 07/19/18 at 2:00 PM, the laboratory manager confirmed the surveyor's findings.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation, record review and interview; the laboratory failed to ensure that the test requisition solicits all required formation. Findings: 1. During survey date 07 /19/18 at 12:30 PM, the surveyor observed how patients tissue specimens were collected, labeled, and sent out for processing. The surveyor observed that a requisition was packed in a biohazard bag, along with the patients' tissue specimen. 2. Review of the requisition revealed that the following information was not included on the requisition when patients' specimens were labeled and sent to the referral lab: a. The test to be performed. b. The source of the specimen 3. During survey date 07/19 /18 at 2:00 PM, the laboratory manager confirmed the surveyor's findings.
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 and interview; the laboratory failed to have a comprehensive procedures manual that reflects its histopathology processes. Findings: 1. Review of the laboratory procedures manual revealed that the procedures manual did not include the following information: 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. Control procedures. c. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. d. 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. e. Description of the course of action to take if a test system becomes inoperable. 2. During survey date 07/19/18 at 2:00 PM, the laboratory manager confirmed the surveyor's findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review and interview; procedures were not approved, signed and dated by the current laboratory director before use. Findings: 1. Review of the laboratory's' procedures manual revealed that the laboratory director had not signed and dated the procedures that were currently being used. 2. During survey date 07/19/18 at 2:00 PM, the laboratory manager confirmed the surveyor's findings.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review and interview; the laboratory failed to maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). Findings: 1. Review of the laboratory's' procedures revealed that the laboratory had two separate laboratory procedures. The surveyor noted that each of the procedures had different laboratory names. During survey date 07/19/18 at 12:00 PM, in an interview with the laboratory manager, it was revealed that one of the procedures was no longer being used. The manager stated that they took over the facility and brought in their own procedures. There was no documentation to show that the laboratory had discontinued the use of the older procedures. 2. During survey date 07/19/18 at 2:00 PM, the laboratory manager confirmed the surveyor's findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation, review and interview; the laboratory failed to perform and document maintenance activities of its microscope as specified in paragraph (b)(1)(i) of this section. Findings: 1. During survey date 07/19/18 at 12:00 PM walk-through of the laboratory, the surveyor observed that a microscope was the only instrumentation that the laboratory use in the interpretation and diagnosing of patients' tissue specimens. 2. There was no written procedure that defined the laboratory's protocol for maintenance and function checks of its microscope. 3. There was no documentation to show that maintenance and function checks were performed on the laboratory's microscope. 4. During survey date 07/19/18 at 2:00 PM, the laboratory manager confirmed the surveyor's findings.
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 and interview; the test report did not indicate the name and address of the laboratory location where the gross interpretation was performed. Findings: 1. Review of the laboratory procedures revealed that there were two different sets of procedures in the laboratory's procedures manual. One procedure describes the receipt of patients' specimen slide into the laboratory where the pathologists reads and interprets and diagnosis patients' slides; another where patients' surgical specimens are collected and sent to a reference laboratory where the patients' specimens are grossed, processed, and stained. The stained slides, along with a quality control (QC) slide are then sent back to this laboratory where the pathologist interprets and diagnosis the slide. The surveyor noted that this laboratory only performed the interpretation of the diagnosis of patients' slides. 2. Review of 3 patients' test results revealed that the name and address location of where the gross description of patients' specimens was read was not documented in the final reports of 3 of 3 patients test results reviewed. 3. During survey date 07/19/18 at 2:00 PM, the laboratory manage confirmed the surveyor's findings.