Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0420828	09/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dolar Koya Md Sc	333 Chestnut St - Ste 205, Hinsdale, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 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, laboratory records, patients test records and slides; the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct problems identified for its histopathology procedures. Findings include: (see D tag 5203) 1. There was no comprehensive procedures manual that described the step by step process in which the laboratory performed its histopathology procedures. 2. Laboratory records show that there were no unique identifiers used when the laboratory collected and documented patients' tissue specimens. 3. Review of 6 patients' test records revealed that 1 of 6 patients' slides was mislabeled with the incorrect specimen.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on review of survey forms, laboratory's procedures manual, laboratory log, patients' slides, reports and interview with the laboratory director; the laboratory failed to establish and follow written policies and procedures that ensures positive identification and optimum integrity of a patients' specimen from the time of collection or receipt of the specimen through completion of the testing and reporting of results. Findings: 1. Review of survey forms revealed that the laboratory only performs histopathology testing. 2. There were no procedures that described the laboratory process for specimen collecting and testing. 3. Review of the laboratory's log sheets revealed that patients' specimens were not given a unique identifier such as a case number for each different location that a biopsy specimen was collected. In some cases, the same # was given to more than one specimen. 4. On 09/05/19 at 2:30 PM the surveyor selected 6 patients names from the laboratory log. One of which 5 different specimens from 5 different locations were collected and given the same case number for each specimen. 5. 1 of 6 patients' slides was mislabeled with the incorrect specimen location. 6. Review of patients' test reports revealed that a diagnosis was reported for the specimen that was mislabeled. The slide was also sent to the reference laboratory for a 2nd opinion. Records show that the reference laboratory made a diagnosis based on the slide they received from this laboratory. 7. On 09/05/19 at 3:15 PM, the laboratory director 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 of the laboratory's procedures manual and interview with the laboratory director, the laboratory failed to have a procedure manual that included all necessary written instructions that encompass a comprehensive procedure manual. Findings: 1. The procedure manual did not include requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, referral and criteria for specimen acceptability and rejection as described in 493.1242. 2. The procedure manual did not include microscopic examination, including the detection of inadequately prepared slides. 3. The procedure manual did not include step-by-step performance of the procedure, including test calculations and

	interpretation of results. 4. The procedure manual did not include preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. 5. The procedure manual did not include control procedures. 6. The procedure manual did not include corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 7. The procedure manual did not include 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 8. The procedure manual did not include description of the course of action to take if a test system becomes inoperable. 9. On 09/05/19 at 3:10 PM, the laboratory director 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 review of the laboratory's procedures manual, records and interview with the laboratory director; the laboratory failed to perform and document established maintenance activities. Findings: 1. In a procedure titled, "MAINTENANCE OF MICROSCOPE," the following instructions are given: "MICROSCOPE WILL BE SERVICED AS SOON AS SLIGHTEST DIFFICULTY IN MOVEMENT OF PARTS OR REDUCTION IN POWER OF LIGHT SOUCE IS NOTICED.... MICROSCOPE WILL BE SERVICED ANNUALY." 2. Review of microscope maintenance records show that the laboratory uses McCrone Microscope & Accessories to maintain and service its microscope. 3. There was no documentation to show that the microscope was serviced in 2018. 4. On 09/05/19 at 2:45 PM, the laboratory director confirmed the surveyor's findings.
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 laboratory procedures, patients' test records, slides and interview with the laboratory director; the laboratory failed to document control procedures for Hematoxylin and Eosin (H&E) staining. Findings: 1. There were no procedures that described the laboratory's process for how it performs and documents the quality of H&E stain. 2. On 09/05/19 at 3:00 PM, the surveyor requested information for 6 patients' which included the following: a. Patients' test reports b. Patients' slides c.

	Quality Control slides d. Quality Control records 3. There was no Quality Control slide available for 6 of 6 patients' slides reviewed. 4. There was no documentation to show that the quality of the H&E stain was acceptable prior to interpreting 6 of 6 patients' test results. 5. On 09/05/19 at 3:00 PM, the laboratory director told the surveyor that his histopathology specimens are sent to a reference laboratory for processing and staining. He stated that the reference laboratory does not send a QC slide. 6. There was no reference laboratory's client services manual available for review. 7. On 09/05/19 at 3:10 PM, the laboratory director confirmed the surveyor's findings.