Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1018983	02/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Camp Lowell Medical Specialists	3190 N Swan Rd, Tucson, AZ	

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
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 the laboratory's biopsy log, patient's slides and test reports maintained in the patient's Electronic Medical Record (EMR), and interview with the facility personnel, (A) the laboratory failed to ensure positive identification of patient's dermatopathology specimens from the time of collection through completion of testing and reporting of test results; and (B) the laboratory failed to establish 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. Findings include: A1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 700. The laboratory performs the microscopic interpretation of Biopsy specimens. The laboratory utilizes an Electronic Medical Record (EMR) to maintain completed pathology reports. A2. Biopsy specimens are collected by the laboratory, and sent to another CLIA-certified laboratory for processing and slide generation. Prior to sending the specimen for processing, the laboratory records the specimen information and assigns a unique specimen accession number in the biopsy log and also records the assigned accession number on the patient's test requisition. Each slide returned to the laboratory from the processing lab is labeled with two unique accession numbers: the unique accession number assigned by the laboratory at the time of specimen collection as listed in the biopsy log and on the test requisition and a separate accession number assigned by the laboratory who processed the specimen. The patient slide(s) are also labeled with the patient's first

	and last name and date of birth. A3. The laboratory failed to ensure positive identification of the patient's specimen for biopsy interpretation throughout the entire test process on 12/12/2022 (patient F.M.). The biopsy log and test requisition listed the specimen accession number as "A22-453". The patient's slide was labeled with the accession number "A22-513" and "SDA22-00513" (assigned by the processing laboratory). Direct inspection of the patient's slide indicated the laboratory crossed of "A22-513" and manually rewrote the accession number as "A22-453". A4. The facility personnel interviewed during the survey on 2/21/2023 at 1:45pm confirmed the laboratory failed to ensure positive identification of the patient's slide indicated above from the time of collection through completion of testing and reporting of results, as evidenced by the specimen identification error. B1. No documentation was presented for review during the survey conducted on February 21, 2023 to indicate the laboratory established 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. B2. The facility personnel interviewed during the survey on 2/21/2023 at 1: 50pm confirmed the laboratory could not produce evidence of a written policy and procedure as indicated above.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of established quality assessment (QA) policies and interview with the facility personnel, the laboratory failed to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 700. 2. The laboratory's established policy QA policy presented for review failed to include information to monitor, assess and when indicated, correct problems identified in the general laboratory systems, including but not limited to, ensuring the positive identification of patient specimens. See D5203 for findings. 3. The facility personnel interviewed on 2/21/2023 at 2:05pm acknowledged that the laboratory's QA processes at the time of the survey failed to monitor, assess and correct problems identified in the general laboratory systems.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (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 tissue pathology reports and interview with the facility personnel, the laboratory failed to have three pathology reports signed by the individual who performed the examination and made the diagnosis. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 700. The laboratory performs the microscopic interpretation of Biopsy specimens. The laboratory utilizes an Electronic Medical Record (EMR) to maintain completed pathology reports. 2. Three out of three biopsy test reports reviewed in the EMR during the survey (A21-406, A22-68 and A22-453) failed to include the signature of the individual who performed the examination and made the diagnosis. 3. The facility personnel interviewed during the survey on 2/21 /2023 at 1:05pm confirmed that the pathology reports indicated above were not signed by the individual who performed the examination and made the diagnosis.
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 pathology test reports maintained in the patients' Electronic Medical Record (EMR) and interview with the facility personnel, the laboratory failed to include the test report date on the final test report. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 700. The laboratory performs the microscopic interpretation of Biopsy specimens. The laboratory utilizes an Electronic Medical Record (EMR) to maintain completed pathology reports. 2. Three out of three biopsy test reports reviewed in the EMR during the survey (A21-406, A22-68 and A22-453) failed to include the test report date (date the examination was performed and the diagnosis was made) on the final test report. 3. The facilty personnel interviewed during the survey on 2/21/2023 at 1:10pm acknowledged the test report date was missing from the final test reports maintained in the EMR.