Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2159960	06/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Regency Specialties	14725 W Mountain View Blvd, Suite 275, Surprise, 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
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 lack of a microscope maintenance policy and interview with the laboratory director, the laboratory failed to establish a microscope maintenance policy that indicates specific routine maintenance procedures, as well as scheduled preventative maintenance procedures. Findings include: 1. No documentation was presented for review during the survey performed on June 15, 2022 to indicate the laboratory established a microscope maintenance policy, including routine and preventative maintenance. 2. The laboratory director acknowledged that no microscope maintenance policy was established by the laboratory. 3. The laboratory's annual test volume under the sub-specialty of Histopathology is approximately 19,200.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)

	The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of pathology test records and interview with the laboratory director, the laboratory failed to maintain a record system that includes the identity of the individual who performs the gross description on histopathology specimens. Findings include: 1. The laboratory performs the gross description on skin biopsies under the sub-specialty of Histopathology, with an approximate annual test volume of 19,200. The laboratory utilizes an EMR (Electronic Medical Record) to maintain patient test records and test reports. 2. No documentation was presented for review during the survey performed on June 15, 2022 to indicate the laboratory maintained a record system to include the identity of the personnel who performs the gross description on pathology specimens. 3. The laboratory director confirmed the laboratory failed to maintain a record system at the time of the survey that includes the identity of the testing personnel who performs the gross description on patient specimens.