

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2162146	(X3) Date Survey Completed 05/01/2024
Name of Provider or Supplier Saguaro Dermatology Associates, Llc	Street Address, City, State 3400 E Mcdowell Road, Phoenix, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed follow the established QA policy titled "Quality Assurance Policy" 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 the microscopic interpretation (reading/diagnosis) of patient specimens under the subspecialty of Histopathology, with an approximate annual test volume of 310. 2. The laboratory's established QA policy presented for review during the survey conducted on 5/1/2024 states, "Each Mohs surgeon will have 2 slides from each year (1 from Jan-June and 1 from July-Dec) in which Frozen Section Biopsies are performed pulled at random. The slides will be pulled to ensure that everything is recorded accurately....A reviewing Mohs surgeon will verify the diagnosis and sign off on the paperwork." 3. No documentation was presented for review during the survey conducted on 5/1/2024 to indicate the laboratory followed the established QA policy as indicated above. 4. The facility personnel interviewed on 5/1/2024 at 10:05 AM confirmed the laboratory failed to follow their established QA policy as indicated above.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on lack of quality assessment (QA) documentation, review of the laboratory's established QA policy titled "Quality Assurance Policy", and interview with the facility personnel, the laboratory failed to follow the established QA policy to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory performs the microscopic interpretation (reading/diagnosis) of patient specimens under the subspecialty of Histopathology, with an approximate annual test volume of 310. 2. The laboratory's established QA policy titled "Quality Assurance Policy" states, "This laboratory will record all activities, quality assessment monitoring, errors and problems." 3. No documentation was presented for review to indicate the laboratory documented quality assessment activities per the established policy. 4. The facility personnel interviewed on 5/1/2024 at 10:00 AM confirmed the laboratory failed to provide documentation of QA activities as indicated in the established policy listed above.