

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2054440	(X3) Date Survey Completed 09/12/2022
Name of Provider or Supplier Center For Dermatology, Pllc-Chandler	Street Address, City, State 10440 E Riggs Rd, Ste 160, Chandler, 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 to follow established QA policies and procedures to monitor, assess and correct problems identified in the laboratory. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 600. 2. The laboratory's established policy QA policy (Policy# PP-18) reviewed during the survey states, "Our laboratory uses a quality assessment program which includes monthly review of charts/case reviews to ensure the processes were performed and documented correctly and that there were no significant errors in the processes, documentation, or diagnosis." 3. No QA documentation was presented for review from 2020 through the date of the survey, 9/12/2022, to indicate the laboratory performed a monthly review on charts/cases as indicated in the above referenced QA policy. 4. The facility personnel interviewed on 9/12/22 at approximately 10:34am confirmed that the laboratory failed to perform and document monthly QA activities during 2020 through 9/12/22, as indicated in the laboratory's established QA policy.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>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</p>

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 frozen biopsy test reports and interview with the facility personnel, the laboratory's record system failed to include the correct identity of the individual who performs the gross description on histopathology specimens. Findings include: 1. The laboratory performs the gross description on frozen biopsies under the sub-specialty of Histopathology, with an approximate annual test volume of 9. 2. Review of the frozen biopsy report, accession# PSL-FBX-01, from May 18, 2022 listed the Gross Description as, "...Grossing by: KB". 3. The CMS-209, Laboratory Personnel Form submitted during the survey conducted on September 12, 2022 did not include a testing personnel with the initials, K.B. The facility personnel stated that "K.B." does not perform testing on patient specimens. 4. The facility personnel interviewed during the survey on 9/12/22 at approximately 10:12am confirmed the frozen biopsy report indicated above failed to include the correct identity of the testing personnel who performed the gross description and confirmed that "K.B." does not perform grossing on patient specimens.