

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2159960	(X3) Date Survey Completed 01/24/2020
Name of Provider or Supplier Regency Specialties	Street Address, City, State 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test reports for Mohs testing, test records for Mohs testing and interview with the facility personnel, the laboratory failed to include the test result on one test report reviewed during the survey. Findings include: 1. The laboratory began Mohs testing in the sub-specialty of Histopathology on 06/04/2019, with an approximate annual test volume of 950. The laboratory utilizes an electronic medical record (EMR) system to document the test procedure and test results. 2. One out of three Mohs test reports reviewed during the survey (M19-218) failed to include the final test result for Mohs. The Mohs Map for this patient indicated 2 stages were performed. The EMR reviewed for this patient failed to include information regarding Stage 2, including the final test result. 3. The facility personnel confirmed that the EMR for case# M19-218 failed to include the final test result.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of Mohs surgery slides, Mohs map, patient test reports, Mohs patient log and interview with the facility personnel, the laboratory failed to identify errors found with patient identification for one out of three Mohs cases reviewed. Findings include: 1. Review of the Mohs patient test log and the Mohs slides for case# M20-013 indicated the patient name as M.S. 2. Review of the Mohs Map and Mohs test report (maintained in an electronic system) for case# M20-013 indicated the patient name as T.S. 3. The facility personnel confirmed that the patients' name referenced above was incorrectly listed on the slides and on the Mohs patient log.