Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2109941	01/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Banner University Medical Center Tucson	3838 N Campbell Ave Bldg 1, 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
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 quality assessment (QA) policies and interview with the facility personnel, the laboratory failed to perform and document quality assessment activities as indicated in laboratory policy. Findings include: 1. The laboratory performs patient testing in the sub-specialty of Histopathology with an approximate annual test volume of 700. 2. The laboratory's established policy, #4089, Version 2, states, "Pick and review two (2) patients randomly on a semi-annual basis. Document all findings of this review on Laboratory Specimen Management form. Keep QA forms under the month this review was conducted or place in the next month's section if a follow-up review is scheduled. Review all reports for appropriate procedures". 3. No QA documentation was presented for review to indicate the laboratory performed and documented QA reviews as outlined in laboratory policy during 2018 and 2019. 4. The facility personnel confirmed that the laboratory failed to perform and document the semi-annual QA review as stated in policy during 2018 and 2019.
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 the laboratory's test reports for Mohs testing from 2018 and 2019, test records for Mohs testing and interview with the facility personnel, the laboratory failed to include the test result on two out of four test reports reviewed during the survey. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 700. The laboratory utilizes a Mohs Map as the test report. The Mohs Map contains an area for the physician to document whether or not the margins are clear. 2. Two out of four Mohs test reports reviewed during the survey (W19-113 and W18-077) failed to include the final test result for Mohs, including the number of stages performed. 3. The facility personnel confirmed that the Mohs Maps indicated above failed to include the final test result.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of policies for review, review of patient test reports and interview with the facility personnel, the laboratory failed to establish policies for documenting Mohs Maps and reporting and maintaining test reports in an electronic record system. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the sub-specialty of histopathology, with an approximate annual test volume of 700. The laboratory utilizes a Mohs map as the test report, as well as documenting the results in an electronic medical record (EMR). 2. On the date of the survey, 01/17 /2020, no documentation was presented for review to indicate the laboratory had established policies and procedures in place to indicate the laboratory's process for documenting the Mohs map. 3. On the date of the survey, 01/17/2020, no documentation was presented for review to indicate the laboratory had established policies and procedures in place to indicate the laboratory's process for reporting and maintaining test reports in an electronic record system.. 4. The facility personnel confirmed that the laboratory failed to have established post-analytic policies in place related to Mohs map and test reports that are maintained electronically.