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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D2109941 | (X3) Date Survey Completed 04/10/2018 |
| Name of Provider or Supplier Banner University Medical Center Tucson | Street Address, City, State 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 |
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| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of accuracy verification documentation and interview with the facility personnel, the laboratory failed to verify the accuracy of dermatopathology testing at least twice annually in 2016 and 2017. Findings include: 1. The laboratory began patient testing under the sub-specialty of Histopathology in March 2016, with an approximate annual test volume of 720. 2. During the survey conducted on April 10, 2018, the laboratory presented documentation of accuracy verification for Mohs cases that were reported in 2016 and 2017 but were not reviewed by an outside dermatopathologist until March of 2018. There were no cases sent out for accuracy verification during 2016 and 2017. 3. The facility personnel acknowledged that no cases were sent out for review during 2016 and 2017.</p> |
| 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 the laboratory's established policies and interview with the facility personnel, (A) the laboratory failed to establish policies related to accuracy</p> |

verification for Dermatopathology testing performed by the laboratory and (B) the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the sub-specialty of Histopathology, with an approximate annual test volume of 720. A2. No documentation was presented during the survey to indicate the laboratory had established policies related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. A3. The facility personnel confirmed that the laboratory did not have an established policy in place at the time of the survey for the verification of accuracy process used for dermatopathology testing performed by the laboratory. B2. No documentation was presented for review to indicate the laboratory had established quality assessment policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems. B3. The facility personnel confirmed that the laboratory did not have quality assessment policies and procedures in place at the time of the survey.