Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0970146	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Michael J Huether Md Pc	5980 N La Cholla Blvd, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2017. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 3,582. 2. No documentation was presented for review during the survey conducted on April 3, 2018 to indicate the laboratory verified the accuracy of testing at least twice annually during 2017 for the following tests: Slide interpretation for Mohs testing, biopsy interpretation and the MART-1 Melonoma special stain used on patient specimens. 3. The facility personnel stated that it is the practice of the laboratory to send 6 Mohs cases, 6 Biopsies cases and 1 Melanoma stain case every 6 months to another qualified physician for accuracy verification, however the laboratory failed to send the cases for verification in 2017.
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 the laboratory's established Quality Assessment policies and interview with the facility personnel, the laboratory failed to establish policies related to accuracy verification for Dermatopathology testing performed by the laboratory. Findings include: 1. The laboratory performs patient testing under the sub-specialty of Histopathology, with an approximate annual test volume of 3,582. The laboratory performs slide interpretation for Mohs testing, slide interpretation for Biopsies and the MART-1 Melanoma stain on certain specimens as outlined in laboratory policy. 2. 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. 3. 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 for dermatopathology testing performed by the laboratory.
D5787	TEST RECORDS CFR(s): 493.1283(a) 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 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 patient test records for Mohs testing and interview with the facility personnel, the laboratory failed to maintain a record system that positively identified the specimen. Findings include: 1. The laboratory performs patient testing in the sub-specialty of histopathology, with an approximate annual test volume of 3.582. The laboratory performs biopsies, if warranted, while the patient is at the laboratory for a scheduled Mohs procedure. The laboratory utilizes a "Mohs Surgery or Excision Map" to document the test information and final test results for Mohs and Biopsy testing. 2. Review of the Mohs Surgery or Excision Map from testing performed on 10/26/2016 for patient R.S., indicated the patient had Mohs performed on one site, and had two biopsies performed, one from the Left Ventral Proximal Forearm and one from the Right Lat. Upper Back. 3. During the survey, the laboratory presented the biopsy slide for review for the case mentioned above that was labeled with the following information: Last name of patient, First initial of patient, Date of testing, Patient's Date of Birth and "Bxs 1 & 2". Both biopsy specimens were mounted on the same slide. 4. The laboratory failed to maintain a slide labeling system for the biopsy specimen referenced above that positively identifies each biopsy specimen tested, since both specimens from different locations were mounted on the same slide and the slide label only indicated "Bxs 1 & 2". 5. The facility personnel confirmed that the biopsy specimen identification could not be determined from the information written on the slide label for the case indicated above.