Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2099732	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners	3508 S Lamar Blvd #300, Austin, TX	

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 review of the laboratory's policies, quality assurance records from 2016 through 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS testing in 2017. Findings included: 1. A review of the laboratory's policy titled Proficiency Testing MOHS Micrographic Surgery Skin Specimens found " Semi-annually, the Tech or the High Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopathologist. NO differential diagnosis will be offered with the specimen. The slide may be labeled Proficiency Test by the Sending laboratory for the records of the reference laboratory. Upon receipt of the pathology report from the Dermatopathologist, diagnoses of the slide specimen will be matched to the in-house diagnosis by the physician. If the diagnoses match, the reports are attached and placed in Proficiency Testing Located in the quality control Manual. In the event the pathology report from the dermatopathologist, diagnosis does NOT match the inhouse diagnosis by the physician, an internal slide will be sent, by the tech or risk manager to another outside laboratory chosen from the list below, for microscopic examination. Results of each proficiency test will be entered in a log and kept in the laboratory management manual." 2. A review of the laboratory's MOHS testing accuracy assessment records from 2016 through 2018 found: a. Two cases sent to Dr. LL for review on December 20, 2016 with no documentation of the date of review. b. Two cases sent to Dr. LL for review on December 27, 2017 with documented review date of 1-4-18. c. Two cases sent to DR. JD for review on December 27, 2017 with no documentation of the date of review. 3. Interview of the

	histotechnician conducted on September 19, 2018 at 10:12 AM confirmed that the reports did not have dates of review and that no other MOHS PT was available for review.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Review of policies and procedures and interview of facility personnel found that the procedures used by testing personnel had been approved signed and dated by the current laboratory director. The Findings included: 1. Review of the procedures contained in the procedure manual found a Laboratory Director's approval (for the previous laboratory director) dated 08/118/2015. There was no documentation of approval by the current laboratory director. 2. Interview of the histotechnician conducted on September 19, 2018 at 10:20 AM confirmed that procedures had not been approved by the current laboratory director who became the new laboratory director on February 3, 2017.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Review of policies and procedures operators guide and interview of facility personnel found that the laboratory director failed to ensure that an approved procedure was available to all testing personnel . (See D5407)
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a

	reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Review of the CMS 116, and interview of the facility personnel found that the laboratory failed to notify HHS of a change in ownership within 30 days of any change. The findings included: 1. Review of the CMS 116 provided during the onsite recertification inspection conducted on September 19, 2018 found that the ownership information provided (name, Federal Tax ID) did not match the ownership information in the CMS 116 database. Notification of the change in ownership to the state agency was requested but not provided. 2. Interview of the histotechnician and corporate representative conducted on September 19, 2018 at 09:27 AM found that the laboratory changed ownership in 2017 (exact date unknown). The corporate representative thought that the change of ownership had been submitted but had no documentation of the notification to the state agency.