Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1021286	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners Georgetown	700 San Gabriel Village Blvd, Ste 105, Georgetown, 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
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
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 quality assurance records from 2018 through 2020 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for KOH preparations in 2018 and 2019 . Findings included: 1. A review of the laboratory's Parasitology and KOH Competency Exams from 2018 through 2020 found documentation of verification of the accuracy of results for KOH preparations done once each year in 2018 and 2019. The laboratory was not enrolled in a CMS approved proficiency testing program for Clinical Microscopy. Dates of competency exams performed were February 15, 2018 and August 14, 2019. 2. An interview with the clinic manager conducted on January 3, 2020 at 2:47 PM confirmed the laboratory was neither enrolled in a proficiency testing program nor did the laboratory verify the accuracy of the test results for KOH at least twice a year in 2018 or 2019.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of laboratory quality control records, policies and procedures, surveyor observation, patient records, and interview of facility personnel it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6102, D6103, and D6120.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Review of personnel Records and interview of facility personnel found that the laboratory director failed to ensure that testing personnel had the appropriate education prior to performing gross analysis of patient specimens for Histopathology. (See D 6171)
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: The laboratory director failed to ensure there was a procedure in place to assess the competency all testing personnel involved in preanalytic, analytic and postanalytic testing of histopathology specimens. (See D6120)
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and interview, the Technical supervisor failed to evaluate the competency of all testing personnel performing histopathology procedures, using the six required components for competency. The findings included: 1. Review of the laboratory's personnel records found no documentation of Competency assessments for physicians performing histopathology testing in 2018 and 2019 that included the six required elements: Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; Direct observation of performance of instrument maintenance and function checks; Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; Assessment of problem solving skills; The laboratory offered Peer reviews performed in 2018 and 2019 as competency assessment for six of nine testing personnel 2. Interview of the office manager conducted on February 3, 2020 at 2:39 PM confirmed that peer review evaluations was all that was available to assess the competency of physicians performing Histopathology.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of the Laboratory Personnel Report, personnel records and staff interview, it was revealed that three of three testing personnel performing high complexity testing (gross analysis of tissue specimens) did not have the appropriate documented training required to perform high complexity testing. (refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or

other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of the CMS report 209 laboratory personnel report, personnel records and interview of facility personnel the laboratory failed to have documented training for three of three testing personnel performing gross analysis of patient tissue specimens . The findings included: 1. Review the CMS report 209 laboratory personnel report found seven testing personnel listed for high complexity testing. 2. Review of personnel files found no documented training for testing personnel performing gross examinations including the inking, scoring and dissection of tissue specimens. Testing person 7 (hire date May 24, 2017) Testing person 8 (hire date December 10, 2018) Testing person 9 (hire date July 23, 2018) 3. Interview of testing person seven on the CMS report 209 Laboratory Personnel Report conducted on February 3, 2020 at 3:52 PM confirmed that there was no documentation of training available for review. Interview of the office manager confirmed that the laboratory added the technical component of histopathology to its certificate through a 2018 change in ownership.