Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1103581	11/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Dermatology & Cosmetic Surg	800 S Highway 281, Marble Falls, 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
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 upon review of the CMS 116 application, laboratory records and staff interview, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) at least twice annually in 2018 and 2019. Findings included: 1. Review of the laboratory's CMS 116 obtained during the survey found that the laboratory annual test volumes for KOH and wet mounts was 12. 2. The Laboratory had no documentation of participating in a proficiency testing program for Clinical Microscopy in 2018 or 2019. 3. Review of the KOH log book found documentation for one instance of laboratory director review of KOH results conducted on April 23, 2018. No other documentation was made in the KOH log book. 4. Interview of the Histotechnician conducted on November 14, 2019 at 10:35 AM confirmed that the laboratory did perform KOH wet prep testing ,and that results of the twice annual accuracy assessments were supposed to be documented in the KOH log book, initialed by the laboratory director in the sign off column.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

	when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: A. Observations, and interview of facility personnel found that the laboratory failed to ensure all secondary containers of stains and or solutions were labeled to indicate the contents, storage requirements, preparation and expiration dates and any other pertinent information regarding the contents. The findings included: 1. Observations made in the laboratory on November 14, 2019 at 09:59 AM found two brown dropper bottles labeled Saline next to the microscope. No primary containers of saline were in the laboratory. 2. Interview of the histotechnician was asked to provide the primary source of the aliquotted saline in the dropper bottles and they were not provided. In interview conducted on November 14, 2019 at 10:04 AM she stated" she doesn't know what they are used for and it is not used by testing personnel". The laboratory did not include all information regarding storage, preparation and expiration dates as well as any other pertinent information regarding the contents of the secondary containers.
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: Review of pathology reports and interview of facility personnel found that the laboratory failed to ensure the name and address of the laboratory performing the microscopic analysis of tissue specimens obtained during Mohs surgical procedures appeared on one of four reports reviewed. The findings included: 1. Review of four final pathology reports found no documentation of the name and address of the laboratory performing microscopic analysis for Accession HCM-19-012 performed February 1, 2019 2. Interview of the histotechnician conducted on November 14, 2019 at 10:49 AM confirmed that the name and address of the laboratory performing the microscopic tissue examination did not appear on the final report. She stated "the medical assistant failed to change the location of the laboratory in the notes. The address on the final report defaults to the primary office if the address is not changed."
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 the CMS report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that the laboratory director failed to ensure that testing personnel were evaluated for competency in performing KOH testing in 2018 and 2019. Findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory designated one testing personnel performing moderate complexity procedures (KOH wet mount). 2. Review of personnel records found no documentation of annual competency assessments for testing persons two in 2018 and 2019. 3. Interview of the histotechnician conducted on November 14, 2019 at 10:35 AM confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel files, policies and procedures, patient test records and staff interview, it was revealed the technical consultant failed to assess the competency for one of two testing personnel performing KOH wet mounts at least annually during the first year of testing patient specimens. THIS IS A REPEAT DEFICIENCY FROM THE NOVEMBER 2017 INSPECTION Findings included: 1. Review of personnel records found no assessment performed in the first year of testing for testing person two listed on the CMS report 209 Laboratory Personnel Report. Testing person two was hired in 2014. There was no documentation of competency assessment by the technical consultant performed in 2018 or 2019. A competency assessment dated 2018 was performed by a previous testing personnel instead of the technical consultant. 2. A log for competency assessments (submitted as corrective action for the 2017 citation) was found with no documentation of competency assessments performed. 3. Interview of the histotechnician conducted on November 14, 2019 at 10:35 AM confirmed that the technical consultant failed to perform and document annual competency assessments for testing person two in 2018 and 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:

	The laboratory director failed to provide overall direction and and management of the laboratory. See D 6079)
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of written laboratory policies and procedures, laboratory records, and interviews it was determined that the Laboratory Director (who was also Technical Supervisor) failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. The laboratory director failed to ensure that verification of accuracy of results for KOH testing were performed at least twice each year in 2018 and 2019. (See D 5217) The laboratory director failed to ensure all reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, were labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (See D 5415) The laboratory director failed to ensure that the name and address of the testing location appeared on the final test report. (See D 5805) The laboratory director failed to ensure that competency assessments were performed for all testing personnel performing KOH testing at least annually. (See D 6054) Observations and interview of facility personnel found the Laboratory director failed to notify the state agency within 30 days of any change in location. The findings included: 1. The Surveyor arrived at the laboratory provided address of 507 FM 2147 Suite 202 in Marble Falls November 14, 2019 at 09:29 AM. The suite was empty and leasing information was posted in the window. An Internet search for the facility resulted in the address of 800 S. Highway 281. 2. Interview of the histotechnician conducted on November 14, 2019 at 9:45 AM confirmed that the laboratory moved to its current location "approximately 2 years ago, and she just thought about notifying CLIA of the new address".