

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2138736	<b>(X3) Date Survey Completed</b> 07/12/2019
<b>Name of Provider or Supplier</b> Westlake Dermatology & Cosmetic Surgery	<b>Street Address, City, State</b> 200 N Lakeline Blvd Suite A, Cedar Park, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1423 Condition: Laboratories performing moderate complexity testing; testing personnel
<b>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, laboratory records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS histopathology and KOH testing. Findings included: 1. Review of the laboratory's policy and procedures found under the heading Slide Review: "The lab director will have the histotechnician pull slides for outside review twice annually, in June and November, unless a review has already been done for the preceding six month period. The history technician will then file the completed review form in the manual. Once the review has been done, and slides are refiled. " 2. There were no records available for review for the assessment of accuracy of results for the Mohs testing or KOH and the laboratory did not participate in a proficiency testing program in 2017, 2018 or 2019. 3. Interview of the histotechnician conducted on July 12, 2019 at 9:28 AM confirmed that no records for accuracy assessments done were available for review. She stated that she "knew she sent them off but she has no idea where they are".</p>
<b>D5413</b>	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Observations, review of the operators manual and interview of facility personnel found that the laboratory failed to ensure that the temperature and humidity of the room where the Leica cryostat was used for cutting tissue met the manufacturer specifications. Findings included: 1. Observations made during the tour the facility found that the laboratory had no means of measuring the temperature and humidity of the room where the Leica cryostat was used for cutting patient tissues. 2. Review of the operators manual found under the heading installation site requirements - "the place of installation must meet the following requirements: no direct sunlight, mains power socket at a distance no greater than 2.5 m (linked of power cord equals 2.5 m) - no extension cords must be used! no drafts (air-condition outlets etc.), even floor, virtually of operation free floor, and will freely and easily accessible room temperature maximum 35C, (lesson 22C recommended), relative humidity maximum 60%, only for indoor use." 3. Interview of the histotechnologist conducted on July 12, 2019 at 9:51 AM confirmed that the laboratory did not have a means of monitoring the temperature and humidity of the room but used the thermostat in the hallway as their source of temperature and humidity readings

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

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 semiannually during the first year of testing patient specimens. Findings included: 1. Review of personnel records found no assessment performed in the first year of testing for testing two listed on the CMS report 209 Laboratory Personnel Report. Testing person two was hired August 22, 2017. There was no documentation of initial training and no documented competency assessments. 2. Review of patient test records found that testing person two tested for patient specimens for KOH on the following dates: PMS 255249 date of service October 11, 2018. PMS 125195 date of service January 19, 2019. PMS 41160 date of service February 19, 2019. PMS 263964 date of service March 18, 2019 3. Review of the policy and procedure manual found under the heading personnel assessment: "if the laboratory has employees, the laboratory director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." 4.

Interview of the histotechnician conducted on July 12, 2019 at 9:51 AM confirmed that the laboratory failed to perform and document semiannual competency assessments during the first year of testing for testing person two.

**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. Findings included: 1. Review of personnel records found no assessment performed in the first year of testing for testing two listed on the CMS report 209 Laboratory Personnel Report. Testing person two was hired August 22, 2017. There was no documentation of initial training and no documented competency assessments. 2. Review of patient test records found that testing person two tested for patient specimens for KOH on the following dates: PMS 255249 date of service October 11, 2018. PMS 125195 date of service January 19, 2019. PMS 41160 date of service February 19, 2019. PMS 263964 date of service March 18, 2019 3. Review of the policy and procedure manual found under the heading personnel assessment: "if the laboratory has employees, the laboratory director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." 4. Interview of the histotechnician conducted on July 12, 2019 at 9:51 AM confirmed that the laboratory failed to perform and document annual competency assessments during the first year of testing for testing person two.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of the Laboratory Personnel Report, personnel records and staff interview, one of 2 testing personnel did not have documentation of the appropriate education credentials required to perform moderate complexity testing (see D6065 ).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a

chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of laboratory records and staff interview, one of two testing personnel did not have the appropriate education credentials required to perform moderate complexity testing. The findings included: 1. Review of laboratory records found no documentation of education for testing person two listed on the CMS report 209. Education records were requested but not provided. Testing person two was hired August 22, 2017 and tested for patients for KOH wet mount as follows: PMS 255249 date of service October 11, 2018. PMS 125195 date of service January 19, 2019. PMS 41160 date of service February 19, 2019. PMS 263964 date of service March 18, 2019 2. Interview of the histotechnician conducted on July 12, 2019 at 9:14 AM confirmed that education records were not available for review for testing person number two. The history technicians stated that she had requested documentation from testing person number two and was told "she had no idea where her diploma was."

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of laboratory records and staff interview, one of two testing personnel did not have documentation of training completed prior to testing patient specimens for KOH wet mounts. The findings included: 1. Review of laboratory records found no documentation of training for testing person two listed on the CMS report 209. Education records were requested but not provided. Testing person two was hired August 22, 2017 and tested for patients for KOH wet mount as follows: PMS 255249 date of service October 11, 2018. PMS 125195 date of service January 19, 2019. PMS 41160 date of service February 19, 2019. PMS 263964 date of service March 18, 2019 2. Interview of the histotechnician conducted on July 12, 2019 at 9:14 AM confirmed that initial training documentation was not available for review for testing person number two.