

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0682067	<b>(X3) Date Survey Completed</b> 08/13/2018
<b>Name of Provider or Supplier</b> Pinnacle Dermatology	<b>Street Address, City, State</b> 4040 Medical Park Drive, Odessa, 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: 493.1487 Condition: Laboratories Performing High Complexity Testing; testing personnel
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>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. Findings included: 1. A review of the laboratory's policy titled Formal Policy Statement adopted January 16, 2014 found changes made and approved by the laboratory director on April 2, 2015. A handwritten note "change made in proficiency testing specimens sent for annual peer review (not semiannual)" 2. A review of the laboratory's MOHS testing accuracy assessment records from 2016 through 2018 revealed the laboratory performed to accuracy assessments in 2016, one accuracy assessment in April 2017 and one accuracy assessment performed on June 1, 2018. The records did not contain documentation of a second assessment in 2017. 3. Interview of the laboratory director conducted on August 13, 2018 and 2:28 PM confirms that he made the changes to the Formal Policy Statement regarding the change from semiannual to annual peer review accuracy assessments and had no other accuracy assessments available for review for 2017.</p>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Observations, review of operators guide, policies and procedures, maintenance logs and interview of facility personnel found that the laboratory failed to follow their own instructions for the the performance of maintenance procedures for the Leica CM 1520 cryo- stats and the demo scientific fume hood as defined in their own written policy titled Quality Control Policies and Documentation. Findings Included: 1. Observations made during the tour the facility found that the laboratory used two Leica CM 1520 cryo- stats for processing patient specimens. Serial numbers for the cryo- stats where serial number 872 and serial number 366. The laboratory also used the Thermo scientific fume hood. 2. Review of the operators manual for the Leica CM 1520 cryo- stats found on page 16 under the heading Installation Site Requirements - "the instrument MUST be connected to a properly grounded socket." Review of the operators manual for the Thermo scientific fume hood found on page 7 under the heading Filter Replacement Schedule - the life of the filter in any specific application is dependent on the rate at which vapor is collected. The best detector for determining that the filters are saturated as the human sense of smell; when it filters no longer absorbed odors from the hood, it is time to change the filters. Recognizing the fact that people become desensitized to smells (we are no longer conscious of the smells in a room after we have been exposed to them for a few hours) it is probably best to establish a fixed arbitrary date (say two months after installation of a new set of filters) when filters are to be discarded and replaced." 3. Review of the laboratory's own written policy titled quality control policies and documentation found on page 1 - "7. Air filter is cleaned as part of the maintenance every six months. 10. Preventive maintenance and grounding checks are done six months." on page 2 - "the cryo- stat is checked every six months for proper functioning".. Further review of the laboratory's written policies and procedures found on page 1 of the procedure titled Quality Assurance Program-"qualifications and training must be documented for all laboratory personnel. Technicians must be evaluated every six months to test competency. Evaluations must be retained in personnel file or manual." 3. Review of the maintenance and service records for the Leica CM 1520 cryo- stats and the Thermo Fisher fume hood found no documentation of maintenance procedures being performed at least once every six months. Service records for the Leica CM 1520 cryo- stats found that maintenance was performed on February 15, 2018 with no other records available for review. Maintenance records for the Thermo Fisher fume hood found that the filter was changed on March 26, 2018 with no prior documentation of filter changes between 2016 and March 26, 2018. 4. Interview of testing for someone conducted on August 13, 2018 at 2:56 PM confirmed there was no other documentation available for review to ensure that the laboratory had performed maintenance procedures at least once every six months as defined in their own policy.

**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 one of two testing personnel performing high complexity testing (grossing) 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 found that one of one testing personnel performing gross analysis of patient tissue specimens failed to have documented training. The findings included: 1. Review the CMS report 209 laboratory personnel report found to testing personnel listed for high complexity testing. 2. Review of personnel files found that testing person one who performed the gross examinations of histopathology had no documentation of training for the inking, scoring and dissection of tissue specimens. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on August 13, 2018 at 1:55 PM confirmed that she was hired in July 2017. She went on to confirm that she Performed gross analysis (inking, scoring and dissection of tissue specimens, and that there was no documentation of training available for review . She states "she was just taking over when someone else was leaving".