

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0955875	(X3) Date Survey Completed 08/19/2020
Name of Provider or Supplier Pinnacle Dermatology Grand Blanc	Street Address, City, State 8245 N Holly Road, Suite 101, Grand Blanc, MI	
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 purpose of this unannounced survey was for complaint #MI00113648. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with Testing Personnel #5 (TP5), the laboratory failed to provide the educational requirements for 1 (TP5) of 5 testing personnel performing moderately complex testing. Refer to D6065</p>
D6065	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p>

high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #5 (TP5), the laboratory failed to ensure personnel performing fungal culture testing using Dermatophyte Test Media were qualified for 1 (TP5) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. An interview with TP5 on 8/19/2020 at 11:24 am revealed TP5 performs testing of fungal cultures using Dermatophyte Test Media. 2. A record review of the laboratory's personnel records revealed a lack of documentation of education for TP5. 3. A request by the surveyor for TP5's education documents was made on 8/19/2020 at 11:24 am and the documents were not made available. 4. The laboratory was given an additional 7 days to supply the necessary education documents. The documents were not received.

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 record review and interview with Testing Personnel #5 (TP5), the laboratory failed to provide the educational requirements for 1 previously employed testing personnel performing highly complex 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 record review and interview with Testing Personnel #5 (TP5), the laboratory failed to ensure personnel performing gross examinations of Mohs micrographic surgery tissue specimens were not qualified for 1 testing personnel employed from July 2019 to June 2020. Findings include: 1. An interview with TP5 on 8/19/2020 at 10:42 am revealed a testing personnel previously employed by the laboratory from July 2019 to June 2020 had performed gross examination of Mohs micrographic surgery tissue specimens during the duration of their employment and was not qualified. 2. A record review of the laboratory's personnel records revealed a lack of documentation of education for the previously employed testing personnel. 3. A request by the surveyor for the previously employed testing personnel's education documents was made on 8/19/2020 at 10:42 am and the documents were not made available. 4. The laboratory was given an additional 7 days to supply the necessary education documents. The documents were not received.

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:

. Based on record review and interview with Testing Personnel #5 (TP5), the laboratory failed to include all testing personnel performing both moderate and high complexity testing on the CMS-209 form when requested during the 10/7/2019 survey. Findings include: 1. A review of the surveyor notes from the 10/7/2019 survey revealed the surveyor requested pre-survey paperwork, including the CMS-116 and CMS-209 forms, to be completed on 10/7/2019 at 8:53 am. 2. An interview with TP5 on 8/19/2020 at 10:42 am revealed a previously employed testing personnel employed from July 2019 to June 2020 was performing gross tissue examinations for Mohs micrographic surgery during this time. 3. An interview with TP5 on 8/19/2020 at 11:24 am revealed TP5 was performing fungal culture readings of Dermatophyte Test Media at the time of the 10/27/19 survey. 4. A review of the 10/7/19 survey CMS-209 form revealed a section titled "Instructions" stating, "List below all technical personnel, by name, who are employed by the laboratory. Check the appropriate column for each position held." 5. A review of the 10/7/19 survey CMS-209 document revealed it did not include two testing personnel (TP5 and the testing personnel employed from July 2019 to June 2020) employed by the laboratory during the time of the survey.