Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2140742	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Dermatology	10720 W 165th St, Orland Park, IL	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with a laboratory representative; the laboratory failed to ensure established safety procedures were observed to ensure protection from chemical hazards as no material safety data sheets (MSDS) were available for hazardous chemicals used in the processing of histopathology specimens. Findings include: 1. Direct observation of the laboratory facility on 1-14-2020, at 12:20 pm, found no MSDS were available to review for chemicals used to process Mohs histopathology specimens. 2. Review of the laboratory's chemical hygiene plan identified the following chemicals used in this laboratory which should have had MSDS available for review: Hematoxylin, Eosin-y, Alcohol, Xylene, Xylene Substitute, and Formalin. 3. Interview with a laboratory representative at 4:15 pm, on 1-14-2020, confirmed the laboratory failed to have MSDS materials available for review for the chemicals identified in the chemical hygiene plan.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to ensure positive identification of patient specimens throughout the testing process by failing to follow histopathology slide labeling procedures for 1 of 7 dates reviewed for 4 of 4 sets of patient slides. Findings Include: 1. The laboratory's Mohs accession log was reviewed for 7 patient testing dates. 2. Review of patient slides for 01-03-2020 found the slides for 4 of 4 patients' were mislabeled according to the Mohs accession log. Patient Identification Accession # On Log Accession # On Slide M1 0002 0143 M8 0001 0142 M9 0003 0144 M10 0004 0145 3. On survey date 1-14-2020, at 4:15 pm, the laboratory representative confirmed 4 of 4 sets of patient slides identified above were mislabeled according to the Mohs accession log.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory records, and interview with laboratory personnel; the laboratory failed to check hematoxylin and eosin (H&E) staining material for intended reactivity each day of use for 1 of 7 patient testing dates reviewed for Mohs histopathology testing. Findings Include: 1. Review of the laboratory's policy, "Quality Assurance for Routine Stains", revealed that the laboratory will produce a control slide each day of testing for H&E staining, the laboratory director will determine if the staining is acceptable, and this information will be documented on the quality control log. 2. Review of patient test results for Mohs histopathology testing found for 1of 7 patient testing dates reviewed the laboratory failed to document H&E stain reactivity on the quality control log. Patient Identification Date M7 12-30-2019 3. Direct observation of laboratory slides on 1-14-2020, at 3:30 pm, found the laboratory failed to retain a quality control slide of normal skin stained on 12-30-2019 with H&E, as outlined in the laboratory policy, "Quality Assurance for Routine Stains". 4. Review of the Mohs accession log identified 10 additional patients who had Mohs histopathology testing performed on 12-30-2019. 5. During survey date 01-14-2020, at 4:15 pm, the laboratory representative confirmed H&E stain quality for Mohs histopathology testing failed to be documented on 12-30-2019 and no quality control slide was found for 12-30-2019.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to have a reliable system to ensure that test results are accurately transferred to the final report destination for 3 of 7 patient test records reviewed for Mohs histopathology testing. Findings include: 1. Review of patient test records for Mohs histopathology testing revealed for 3 of 7 patients' the laboratory failed to ensure results indicated on the Mohs maps were correctly transcribed to final report destination (the patient chart - procedure details). Patient Identifier Mohs Map Procedure Detail M3 Stage 1 - Negative Stage 1 - Microscopic tumor was found persisting in 1 of the specimens. M4 Stage 4 - Negative Stage 4 - Microscopic tumor found persisting in "X" of the specimens (No number of specimens provided) M5 Stage 1 - Positive Stage 1 - Microscopic tumor was found persisting in none of the sections of the specimens. 2. Review of the Mohs map and patient chart for patient M4 also found the laboratory failed to identify the number of total specimens and the number of positive specimens for each Mohs stage reviewed and subsequently this information failed to be documented in the procedure detail for each stage in the patient chart. 3. On survey date 1-14-2020, at 4:15 pm, the above findings were confirmed by the laboratory representative.
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 review of the laboratory records and interview with a laboratory representative the laboratory director failed to provide the overall management and direction to maintain proper laboratory operation. The laboratory director must meet the overall management and direction in accordance with 493.1445. Findings include: 1. The laboratory director failed to ensure 3 of 4 testing personnel who conducted high complexity grossing of histopathology specimens met the educational requirements. See D6102. 2. The laboratory director failed to ensure the competency policy was maintained 4 of 4 testing personnel reviewed that perform the grossing of Mohs histopathology specimen. See D6103.
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:

	Based on review of laboratory records and interview with a laboratory representative; the laboratory director failed to ensure 3 of 4 testing personnel who conducted high complexity grossing of histopathology specimens met the educational requirements. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified 3 new testing personnel performing high complexity histopathology testing. 2. Review of personnel records found no qualifying education documentation for 3 of 3 testing personnel performing high complexity grossing of histopathology specimens. See D6171. 3. Review of test volume records revealed of the 866 Mohs blocks documented in the laboratory accession logs in 2019, 772 of those blocks were grossed by personnel that failed to meet the qualification requirements for high complexity testing. 4. On survey date 1-14-2020, at 4:15 pm, the surveyor's findings were confirmed by the laboratory representative.
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: Based on review of laboratory records and interview with a laboratory representative; the laboratory director failed to ensure the competency policy was maintained 4 of 4 testing personnel reviewed that perform the grossing of Mohs histopathology specimens. Findings Include: 1. Review of the document, "Laboratory Competency Assessment Policy", outlined the competency procedure for testing personnel in the specialty of pathology. The policy states the following: "For a new employee, competency assessment evaluation will be performed upon hire, and will be repeated at 6 months, then annually thereafter. All personnel will have annual competency evaluation performed by the laboratory director." 2. Review of competency assessment records for TP#4, 5, 6, and 7 found the following: TP#4 - No annual competency assessment in 2019. TP#5 - Initial training was documented in July of 2018 but no 6 month or 1 year competency assessment was completed in 2019. TP#6 - Initial training was documented in December of 2018 but no 6 month competency assessment was completed in 2019. TP#7 - No training or competency assessment was documented. 3. On survey date 1-14-2020, at 4:15 pm, the above findings were confirmed by a laboratory representative.
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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have 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. Findings Include: 1. The laboratory failed to ensure 3 of 3 new testing personnel (TP) were qualified for high complexity histopathology testing. See 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 laboratory records and interview with a laboratory representative; the laboratory failed to ensure 3 of 3 new testing personnel (TP) were qualified for high complexity histopathology testing. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report), identified 3 new testing personnel performing high complexity histopathology testing: TP#5, 6, and 7. 2. Review of educational documentation for 3 of 3 new high complexity TP identified on the CMS-209 failed to meet the minimum education requirements for high complexity testing. a. TP#5 - No qualifying educational documentation for high complexity histopathology grossing found. b. TP#6 - HS diploma and college course work failed to meet the minimum qualification requirements for high complexity histopathology grossing. c. TP#7 - No qualifying educational documentation for high complexity histopathology grossing found. 3. On survey date 01-14-2020, at 4:15 pm, the above findings were confirmed by the laboratory representative.