

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2058078	(X3) Date Survey Completed 11/28/2018
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 595 William Latham Senior Dr, Bourbonnais, 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
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, laboratory records, and interviews with testing personnel (TP) #6 and a laboratory representative; the laboratory failed to maintain an operable eyewash station. Findings include: 1. Direct observation of the laboratory eyewash on 11-28-2018, at 12:55 pm, found the eyewash disassembled on top of the bathroom sink. 2. Interview with TP#6 on 11-28-2018, at 1:02 pm, confirmed the laboratory eyewash was currently inoperable. 3. Review of the laboratory procedure manual identified the document, "Eye Wash Station", which states a. "The eye wash station is readily available for emergency use" b. "The station is to be checked and documented for proper working order immediately upon the lab opening." c. "Any problems concerning the malfunction of the eye wash shall be immediately reported to the lab director and documented." 4. Review of the 2018 "Eye Wash Station" log failed to document the failure of the eyewash station and was initialed by TP#6 on 11-28-2018 that the eye wash station is readily available and in proper working order. 5. Interview with the laboratory representative on 11-28-2018, at 2:30 pm, confirmed the above findings.</p>
D5217	<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>

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with testing personnel (TP) #6; the laboratory failed to perform 1 of 2 bi-annual method accuracy evaluations for histopathology testing in 2017. Findings Include: 1. Review of the laboratory procedure manual identified the policy, "Proficiency testing MOHS", which stated the following: "Since proficiency testing is not available for Mohs surgery subspecialty, the laboratory will perform test comparison every six months to maintain quality of patient testing." 2. Review of proficiency testing (PT) records for Mohs histopathology testing found only 1 method accuracy evaluation for the year 2017. 3. Interview with TP#6 on 11-28-2018, at 12:00 pm, confirmed the laboratory failed to perform a second method accuracy evaluation for Mohs histopathology testing in 2017.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, direct observation, and interview with laboratory the laboratory representative; the laboratory failed to test each lot and/or shipment of 10% potassium hydroxide (KOH) reagent for intended reactivity and document the results. Findings Include: 1. Review of the laboratory policy and procedure manual identified the procedure, "KOH Procedure Protocol", which stated in step six "if a new KOH 10% (potassium hydroxide) solution bottle is opened, follow steps 3-6 collecting a separate sample to be used as your control. Follow steps below. Document on the KOH Log form the control slide details including lot # and exp date." 2. Direct observation of laboratory testing supplies during a tour of the laboratory on 11-28-2018 at 11:10 am identified 10% KOH reagent, Lot #1807401, which stated it was opened on "3/18". 3. Review of the "KOH LOG" found the laboratory failed to document the testing of the new 10% KOH reagent, lot #1807401. 4. Review of the "KOH LOG" identified 1 of 1 KOH preps performed with the 10% KOH reagent that had not been tested for intended reactivity. 5. Interview with the laboratory representative on 11-28-2017 at 2:30 PM confirmed the laboratory failed to follow control procedures when the 10% KOH reagent, lot#1807401, was put into use.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with a laboratory representative; the laboratory failed to document test results for KOH (potassium hydroxide) preparations on the laboratory KOH testing log. Findings Include: 1. Review of the laboratory policy and procedure manual identified the procedure, "KOH Procedure Protocol", which stated the following in step eight, "The results are documented on the KOH log form". 2. Review of the "KOH log" for testing in 2017 through the date of survey, 11-28-2018, found 4 of 15 patients tested failed to document the test result on the log. 3. Interview with the laboratory representative on 11-28-2018, at 2:30 pm, confirmed that KOH test results failed to be documented on the KOH log.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the laboratory representative; the laboratory failed to identify and correct problems with out of range humidity readings for 11 of 11 months in 2018. Findings Include: 1. Review of the 2018 laboratory log, "Room Temperature/Humidity", stated the acceptable range for humidity was "60% to 75%". 2. Review of the laboratory's temperature log from 2018 found the laboratory's humidity readings were below the acceptable range for 37 of 37 recorded readings. 3. On survey date 11-28-2018, at 2:30 pm, the laboratory representative confirmed the laboratory failed to identify issues with the acceptable level of humidity in 2018.

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 interviews with testing personnel (TP) #6 and a laboratory representative; the laboratory failed to have 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 1 of 7 testing personnel were qualified for high complexity 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 interviews with testing personnel (TP) #6 and the laboratory representative; the laboratory failed to ensure 1 of 7 testing personnel were qualified for high complexity testing. Findings Include: 1. Review of educational documentation for 1 of 7 testing personnel identified on the CMS-209 failed to meet the minimum education requirements for high complexity testing. a. TP#7 - no qualifying educational documentation for high complexity pathology grossing. 2. Interview with TP#6, at 1:30 pm, on 11-28-2018 confirmed TP#7 performed the inking of pathology specimens. 3. Review of competency assessment document, "Initial Assessment of Competence Skill Checklist" for TP#7 confirmed TP#7 was shown to be competent for "proper dye markings/mapping of tissue /orientation technique used". 4. On survey date 11-28-2018, at 2:30 pm, the above findings were confirmed by the laboratory representative.