

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2129169	(X3) Date Survey Completed 03/30/2021
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 1703 Calumet Avenue, Valparaiso, IN	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the procedure manual failed to include step by step instructions for the performance of one of three procedures reviewed ("Automatic Staining Procedure"). Findings included: 1. Review of procedure titled: "Automatic Staining Procedure," last reviewed by the laboratory director on 1-22-2021, indicated the procedure contained a list of stains and a key to the stain rotation schedule ("A=adequate; T=Topped; C=Changed; R=Rotated"). The procedure did not indicate where the stains were to be placed in the stainer, how to properly use the stainer, how long each slide was to remain in a specific stain in the stainer, or when to</p>

top off, change, or rotate a specific stain. 2. Review of "Stainer Rotation Schedule" indicated the following: a. The following stains were changed on 1-22-2021 and 1-27-2021: "95%," water, and "100%". The schedule did not indicate the specific name of the "95%" and "100%" stains. b. The following stains were topped off on 1-22-2021 and 1-27-2021: hematoxylin, bluing, eosin, and xylene "sub." c. The following stains were changed on 2-19-2021 and 3-19-2021: "95%," water, bluing, and "100%." The schedule did not indicate the specific name of the "95%" and "100%" stains. d. The following stains were topped off on 2-19-2021 and 3-19-2021: hematoxylin, eosin, and xylene "sub." 3. On 3-30-2021 at 11:15 AM, SP1, Registered Nurse, acknowledged the "Automatic Staining Procedure" did not indicate where the stains were to be placed in the stainer, how to properly use the stainer, how long each slide was to remain in a specific stain in the stainer, or when to top off, change, or rotate a specific stain. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I), signed by the laboratory director on 3-31-2021, indicated the laboratory's annual volume for histology testing is 250.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation and interview, the laboratory failed to ensure two of two bottles of orange tissue marking ink observed were labeled to indicate the identity, storage requirements, and expiration date. Findings included: 1. On 3-30-2021 at 11:01 PM, while on tour accompanied by SP1, Registered Nurse, the following was observed: a. One bottle, exact size unknown, of orange tissue marking ink was observed in treatment room number 7, located in a wall cabinet. The bottle was labeled "Room 2." The bottle was not labeled with the identity, storage requirements, or expiration date of the ink. b. One bottle, exact size unknown, of orange tissue marking ink was observed in treatment room number 4, located in a wall cabinet. The bottle was labeled "Room 4." The bottle was not labeled with the identity, storage requirements, or expiration date of the ink. 2. In interview on 3-30-2021 at 11:04 PM, SP2, Medical Assistant, acknowledged the following: a. The bottles located in treatment room number 4 and treatment room number 7 contained orange tissue marking ink, used for inking histology specimens. b. The bottles of orange tissue marking ink located in treatment room number 4 and treatment room number 7 were not labeled with their identity, storage requirements, or expiration date. 3. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I), signed by the laboratory director on 3-31-2021, indicated the laboratory's annual volume for histology testing is 250.

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 document review and interview, the laboratory director failed to ensure two of three testing personnel (SP3 and SP4) received training for inking histology specimens. Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 3-29-2021, indicated SP3 and SP4 were testing personnel. 2. Review of personnel records indicated there was no documentation of training for inking histology specimens for SP3 and SP4. 3. Review of policies and procedures indicated the laboratory did not have a policy/procedure for employee training. 4. Review of patient records indicated the following: a. SP3 performed inking on a histology specimen for Patient #7 on 3-5-2020. b. SP4 performed inking on a histology specimen for Patient #6 on 11-13-2020. 5. In interview on 3-30-2021 at 12:17 PM, SP1, Registered Nurse, confirmed there was no policies/procedures regarding employee training and there was no documentation of training for inking histology specimens for SP3 and SP4.

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 document review and interview, two of three testing personnel (SP3 and SP4) failed to meet the qualification requirements of 493.1489 of this subpart 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 document review and interview, two of three testing personnel (SP3 and SP4) failed to qualify to perform high complexity testing. Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" form (CMS-209), signed by the laboratory director on 3-29-2021, indicated SP3 and SP4 were testing personnel. 2. Review of personnel records indicated the following: a. SP3 and SP4 both had a signed "Testing Personnel Job Description," signed by the laboratory director on 3-24-2021, which read: "The testing personnel are responsible for specimen processing, test performance, and for reporting test results..." b. SP3 had a high school diploma and a "Certificate in Histotechnology" dated 6-30-2008. SP3 also had an "undergraduate transcript." dated 6-4-2015, which indicated SP3 earned 12 semester hours of biology and four semester hours of chemistry. The transcript did not indicate SP3 earned a degree. SP3 lacked two semester hours of biology and six semester hours of chemistry, biology or medical laboratory technology in any combination to qualify as a high complexity testing person. c. SP4 had a certificate, dated 6-23-1995, which indicated SP4 "...has satisfactorily completed the prescribed course in histology..." SP4 did not have documentation of a high school diploma or college degree. There was no indication SP4 was performing high complexity testing prior to 4-24-1995. 3. Review of patient records indicated the following: a. SP3 performed inking on a

histology specimen for Patient #7 on 3-5-2020. b. SP4 performed inking on a histology specimen for Patient #6 on 11-13-2020. 4. In interview on 3-30-2021 at 11:55 AM, SP3 confirmed SP3 and SP4 perform inking on histology specimens. On the same date at the same time, SP1, Registered Nurse, confirmed SP3 performed the inking on the histology specimen for Patient #7 and SP4 performed the inking on the histology specimen for Patient #6. 5. In an email dated 4-1-2021 at 11:23 AM, SP1, confirmed the laboratory did not have additional education documentation for SP3. The email further indicated the laboratory was attempting to obtain education documentation for SP4. In a subsequent email, dated 4-5-2021 at 3:33 PM, SP1 indicated the laboratory was having difficulty obtaining education documentation for SP4. No additional education documentation was received for SP3 or SP4 prior to 4-6-2021.