

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0687904	(X3) Date Survey Completed 03/11/2021
Name of Provider or Supplier Ozark Dermatology Clinic	Street Address, City, State 4375 N Vantage Dr Ste 305, Fayetteville, AR	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Through a review of the "Lab Procedures SOPs Personnel", lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to approve, sign, and date the procedures for the permanent sections histopathology lab (Pinnacle Dermatology). Survey findings include: A. During a review of the "Lab Procedures SOPs Personnel" it was determined the manual was not signed and dated by the laboratory director to indicate approval of procedures and that individual procedures within the manual lacked approval signatures and dates of approval. B. In an interview at 9:19 on 3/11/2021, laboratory employee #14 (as listed on the form CMS-209) confirmed the laboratory director had not approved, signed, and dated the "Lab Procedures SOPs Personnel" or any of the procedures contained in the manual.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by:</p>

Through a review of the "Lab Procedures SOPs Personnel" and "Pinnacle Dermopath Specials / IHC" log, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document immunohistochemical stain quality control each time of use. Survey findings include: A. A review of the "Lab Procedures SOPs Personnel" manual revealed procedures for Immunohistochemical staining of tissue samples in the laboratory. B. Through a review of the "Pinnacle Dermopath Specials / IHC" log it was determined 85 IHC stains were performed in February 2021. C. The surveyor requested documentation of positive and negative quality control documentation for immunohistochemical stains but none was provided for review. D. In an interview at 9:19 on 3/11/2021, laboratory employee #14 (as listed on the form CMS-209) confirmed the laboratory did not document positive and negative control results for IHC stains.

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:
Through a review of personnel records contained in the "Lab Procedures SOPs Personnel" manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document initial training in two out of two testing personnel listed on the CMS-209 from the permanent histopathology lab (Pinnacle Dermatology). A. A review of the personnel files in the "Lab Procedures SOPs Personnel" manual, revealed that two of two (personnel #14 and #15 as listed on the form CMS-209) testing personnel working in the permanent histopathology (Pinnacle Dermatology) laboratory failed to have documentation of training for the permanent section procedures listed in the manual. B. In an interview at 9:19 on 3/11/2021, laboratory employee #14 (as listed on the form CMS-209) confirmed employees #14 and #15 failed to have documented training for the laboratory procedures performed in the permanent section histopathology laboratory.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Through a review of personnel records contained in the "Lab Procedures SOPs Personnel" manual, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to authorize two out of two testing personnel

listed on the CMS-209 from the permanent histopathology lab (Pinnacle Dermatology) to perform grossing of tissue specimens without direct supervision. Survey findings include: A. A review of the personnel files in the "Lab Procedures SOPs Personnel" manual, revealed that two (personnel #14 and #15 as listed on the form CMS-209) testing personnel working in the permanent histopathology (Pinnacle Dermatology) laboratory performed grossing of tissue specimens. The personnel files for two out of two testing personnel did not include a written authorization, from the current laboratory director, stating the test processes each was allowed to perform without direct supervision. B. In an interview at 9:19 on 3/11/2021, laboratory employee #14 (as listed on the form CMS-209) confirmed employees #14 and #15 failed to have documented authorizations from the current laboratory director to perform permanent section laboratory procedures without direct supervision.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Through a review of personnel records contained in the "Lab Procedures SOPs Personnel" manual, lack of documentation, and interviews with laboratory staff, it was determined the technical supervisor failed to document semiannual competency assessments for two out of two testing personnel listed on the CMS-209 from the permanent histopathology lab (Pinnacle Dermatology). Survey findings include: A. A review of the personnel files in the "Lab Procedures SOPs Personnel" manual, revealed that two of two (personnel #14 and #15 as listed on the form CMS-209) testing personnel working in the permanent histopathology (Pinnacle Dermatology) had initial competency assessments dated 2/5/2020. No other competency assessments were documented in the first year of performing gross exams and all other test procedures in the permanent histopathology laboratory. B. In an interview at 9:19 on 3/11/2021, laboratory employee #14 (as listed on the form CMS-209) stated that he and employee #15 began working at the end of 2019. He further confirmed employees #14 and #15 had not had competency assessed other than the initial competency dated 2/5/2020.