Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2254561	(X3) Date Survey Completed 03/20/2024
Name of Provider or Supplier Ohioderm Holdings, Inc	**Street Address, City, State** 2200 Timber Trail, Bellefontaine, OH	
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager, the laboratory failed to establish and conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity slide interpretation testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 5,265 out of 5,265 patients tested in the subspecialty of Histopathology on 01/01/2023 through 03/20/2024. Findings Include: 1. The Inspector requested the blind TAV policy and procedure from the Practice Manager. 2. The Inspector requested the blind TAV results for the year of 2023 and 2024 of blind TAV from the Practice Manager. 3. The Practice Manager confirmed the laboratory did not establish and follow a policy and procedure for blind TAV activities at least twice annually for the high complexity slide interpretation testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/20/2024 at 1:22 PM.
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 record review and an interview with the Practice Manager, the Laboratory Director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart for the high complexity slide interpretation testing procedures performed in the subspecialty of Histopathology. This deficient practice had the potential to affect 5,265 out of 5,265 patients tested in the subspecialty of Histopathology from 01/01/2023 through 03/20/2024. Findings Include: 1. The laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. (Refer to D6093) 2. The LD failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided. (Refer to D6094) 3. The LD failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. (Refer to D6106)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager, the Laboratory Director (LD) failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for the high complexity slide interpretation testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 5,265 out of 5,265 patients tested in the subspecialty of Histopathology from 01/01/2023 through 03/20/2024. Findings Include: 1. The Inspector requested the laboratory's quality control policy and procedure from the Practice Manager. 2. The Inspector requested the laboratory's quality control data for the year of 2023 and 2024 from the Practice Manager. 3. The Practice Manager confirmed the laboratory did not establish and follow a policy and procedure for quality control activities for the high complexity slide interpretation testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/20/2024 at 1:22 PM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager, the Laboratory Director (LD) failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for the high complexity slide interpretation testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 5,265 out of 5,265 patients tested in the subspecialty of

	Histopathology on 01/01/2023 through 03/20/2024. Findings Include: 1. The Inspector requested the laboratory's quality assessment policy and procedure from the Practice Manager. 2. The Inspector requested the laboratory's quality assessment data for the year of 2023 and 2024 from the Practice Manager. 3. The Practice Manager confirmed the laboratory did not establish and follow a policy and procedure for quality assessment activities for the high complexity slide interpretation testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/20/2024 at 1:22 PM.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and an interview with the Practice Manager, the Laboratory Director (LD) failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process for the high complexity slide interpretation testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 5,265 out of 5,265 patients tested in the subspecialty of Histopathology from 01/01/2023 through 03/20/2024. Findings Include: 1. The Inspector requested the laboratory's approved procedure manual from the Practice Manager. 2. The Practice Manager confirmed the laboratory did not have an approved procedure manual for the high complexity slide interpretation testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/20/2024 at 1:22 PM.