Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0962984	02/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Center Of Rochester Hills	919 W University Drive Suite 100, Rochester, MI	

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**
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: . Based on record review and interview with the Manager, the laboratory failed to retain histopathology slides for at least 10 years from the date of examination for 7 (2019 to 2012) of 10 years reviewed. Findings include: 1. The surveyor requested slides from one histopathology case performed in March 2012 on 2/10/22 at 10:00 am and it was not made available. 2. An interview on 2/10/22 at 10:02 am with the Manager revealed slides older than 3 years were discarded.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on record review and interview with the Manager, the laboratory failed to establish a policy to assess testing personnel competency for 2 (2020 and 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's policies and

	procedures revealed a lack of policy regarding competency assessments for testing personnel. 2. A review of the laboratory's competency assessment documentation revealed a lack of competency assessment for Testing Personnel #1 in 2020. 3. An interview on 2/10/22 at 10:59 am with the Manager confirmed the laboratory had not established a competency assessment procedure.
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 interview with the Manager, the laboratory failed to verify the accuracy of its microscopic tissue examination testing at least twice annually for 2 (2020 and 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy documentation revealed 14 cases were reviewed on 11/3/21 by a secondary provider. 2. The surveyor requested the first verification of accuracy testing event in 2021 and the two events for 2020 on 2/10/22 at 9:24 am and they were not available. 3. An interview on 2/10/22 at 9:24 am with the Manager revealed the laboratory had not performed verification of accuracy testing for its microscopic tissue examinations at least twice annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Manager, the laboratory failed to include the name and address of the laboratory location where specimen gross examinations were performed for 9 (JS20-848, JS20-389A and B, JS20-691 A and B, JS20-69A and B, JS21-758 A and B, JS21-11154 A and B, JS21 120 A, B, and C, JS22-6A and B, and JS22-73) of 9 patient test reports reviewed. Findings include: 1. A review of the laboratory's patient test reports revealed specimen gross descriptions on the test reports for cases JS20-848, JS20-389A and B, JS20-691 A and B, JS20-69A and B, JS21-758 A and B, JS21-11154 A and B, JS21 120 A, B, and C, JS22-6A and B, and JS22-73. 2. A review of the laboratory's test menu revealed it only performs the microscopic portion of histopathology testing. 3. An interview on 2/10 /22 at 10:59 am with the Manager revealed the gross description is performed by a reference laboratory and confirmed the name and address of the laboratory performing gross descriptions was not included in the patient test reports.