Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2266918	12/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Carefree Dermatology	7208 E Cave Creek Rd Unit E, Cave Creek, AZ	

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 lack of accuracy verification documentation for Mohs and interview with the laboratory director (LD), the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2023. 2. The LD interviewed on 12/16/24 at 2:05 PM confirmed the laboratory failed to verify the accuracy of Mohs testing testing at least twice annually during 2023. 3. The laboratory's reported annual test volume is 200.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established quality assessment (QA) policies and procedures and interview with the laboratory director (LD), the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings

	include: 1. No QA documentation was provided for review during the survey conducted on 12/16/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236. 2. The LD interviewed on 12/16/2024 at 2:10 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements. 3. The laboratory began patient testing in the subspecialty of Histopathology on 12/09/2022, with a reported annual test volume of 200.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the laboratory director (LD), the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. Findings include: 1. No QA documentation was provided for review during the survey conducted on 12/16 /2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. 2. The LD interviewed on 12/16/2024 at 2:10 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the preanalytic systems. 3. The laboratory began patient testing in the subspecialty of Histopathology on 12/09/2022, with a reported annual test volume of 200.
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 lack of quality assessment (QA) policies and procedures and interview with the laboratory director, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1256 and 493.1281 through 493.1289. Findings include: 1. No QA documentation was provided for review during the survey conducted on 12/16/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493.1251 through 493.1256 and 493.1281 through 493.1289. 2. The LD interviewed on 12/16/2024 at 2:10 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic systems. 3. The

	laboratory began patient testing in the subspecialty of Histopathology on 12/09/2022, with a reported annual test volume of 200.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures and interview with the laboratory director, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the postanalytic systems specified in 493.1291. Findings include: 1. No QA documentation was provided for review during the survey conducted on 9/26/2024 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. 2. The LD interviewed on 12/16/2024 at 2:10 PM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified with the postanalytic systems. 3. The laboratory began patient testing in the subspecialty of Histopathology on 12/09/2022, with a reported annual test volume of 200.