Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2265638	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Healthyskin Dermatology	2295 E Vistoso Commerce Loop, Oro Valley, 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
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 review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow QA 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. The laboratory's established QA policy states, "Each of the following systems in our laboratory will be evaluated periodically to be sure that it meets our quality goals...We will keep written records of our review, findings and actions." The policy includes the following systems to monitor under the general laboratory systems requirements at 493.1231 through 493.1236: Confidentiality of Patient Information, Specimen Identification and Integrity, Complaints, Communications, Personnel Competency, Proficiency Testing and Employee Safety. 2. No QA documentation from 8/19/2022 through 12/11/2024 was provided for review to indicate the laboratory followed the policy indicated above to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236. 3. The facility personnel interviewed on 12/11/2024 at 11:40 AM confirmed the laboratory failed to provide documentation of QA activities to monitor, assess and correct problems identified in the general laboratory systems requirements.
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 review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow QA policies and procedures to monitor, assess and correct problems identified in the preanalytic systems requirements specified at 493.1241 through 493.1242. Findings include: 1. The laboratory's established QA policy states, "Each of the following systems in our laboratory will be evaluated periodically to be sure that it meets our quality goals...We will keep written records of our review, findings and actions." The policy includes the following systems to monitor under the preanalytic systems requirements at 493.1241 through 493.1242: Test Request and Specimen Submission, Handling and Referral. 2. No QA documentation from 8/19/2022 through 12/11/2024 was provided for review to indicate the laboratory followed the policy indicated above to monitor, assess and, when indicated, correct problems identified in the preanalytic system requirements specified at 493.1241 through 493.1242. 3. The facility personnel interviewed on 12 /11/2024 at 11:40 AM confirmed the laboratory failed to provide documentation of QA activities to monitor, assess and correct problems identified in the preanalytic systems requirements.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of humidity records for review from 8/19/2022 through 12/11/2024, review of the manufacturer's specifications for the Leica 1510 Cryostat and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized. Findings include: 1. The laboratory utilizes the Leica 1510 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 700. 2. The manufacturer's specifications for the Leica 1510 Cryostat listed an operating relative humidity range of 0%-60%. 3. The laboratory failed to provide documentation demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from 8/19/2022 through the survey date of 12/11/2024. 4. The facility personnel interviewed on 12/11/2024 at 11: 23 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.
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 review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow QA policies and procedures to monitor, assess and correct problems identified in the analytic systems requirements specified at 493.1251 through 493.1283. Findings include: 1. The laboratory's established QA policy states, "Each of the following systems in our laboratory will be evaluated periodically to be sure that it meets our quality goals...We will keep written records of our review, findings and actions." The policy includes the following systems to monitor under the analytic laboratory systems requirements at 493.1251 through 493.1283: Procedure Manual, Test Systems, Quality Control, Comparison of Test Results, Corrective Actions and Test Records. 2. No QA documentation from 8/19/2022 through 12/11/2024 was provided for review to indicate the laboratory followed the policy indicated above to monitor, assess and, when indicated, correct problems identified in the analytic laboratory system requirements specified at 493.1251 through 493.1283. 3. The facility personnel interviewed on 12/11/2024 at 11:40 AM confirmed the laboratory failed to provide documentation of QA activities to monitor, assess and correct problems identified in the analytic laboratory systems requirements.
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 review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow QA policies and procedures to monitor, assess and correct problems identified in the postanalytic systems requirements specified in 493.1291. Findings include: 1. The laboratory's established QA policy states, "Each of the following systems in our laboratory will be evaluated periodically to be sure that it meets our quality goals...We will keep written records of our review, findings and actions." The policy includes the following system to monitor under the postanalytic laboratory systems requirements in 493.1291: Test Report. 2. No QA documentation from 8/19/2022 through 12/11/2024 was provided for review to indicate the laboratory followed the policy indicated above to monitor, assess and, when indicated, correct problems identified in the postanalytic laboratory system requirements specified in 493.1291. 3. The facility personnel interviewed on 12/11/2024 at 11:40 AM confirmed the laboratory failed to provide documentation of QA activities to monitor, assess and correct problems identified in the postanalytic laboratory systems requirements.