Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2084144	02/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
High Desert Dermatology	12241 Academy Rd Ne Ste 204, Albuquerque, NM	

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
D0000	An onsite recertification survey conducted at High Desert Dermatology on February 13, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: 493.1441 - Laboratory Director (high complexity)
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 review of laboratory records, and staff interview, the laboratory director failed to provide overall management and direction as evidenced by: 1. The laboratory director failed to establish a written quality assessment program. Refer to D6094 2. The laboratory director failed to provide an approved procedure manual. Refer to D6106
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 review of laboratory records and staff interview, the laboratory director failed to establish a quality assessment program for 3500 of 3500 patient tests in 2023.

	Findings included: 1. The laboratory was asked to provide documentation indicating a quality assessment program has been established to ensure the quality of laboratory services provided and to identify failures in quality as they occur. No documentation was provided. 2. A review of laboratory records revealed an annual volume of 3500 histopathology patient tests performed. 3. During an interview on 02/13/2024 at 9:00 am with the lead Medical Assistant, confirmed above findings and stated the laboratory does not have written policies and procedures related to the laboratory's quality assessment program.
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 review of laboratory records and staff interview, the laboratory director failed to provide approved procedure manuals available for personnel responisble for the testing process for 3500 of 3500 patients in 2023. Findings included: 1. The laboratory was asked to provide an approved procedure manual available to staff for any aspect of the testing process. No procedures were provided. 2. A review of laboratory records revealed an annual volume of 3500 histopathology tests performed in 2023. 3. During an interview on 02/13/2024 at 9:00 am with the lead Medical Assistant, confirmed above findings and stated the laboratory does not have written policies and procedures related to the laboratory's testing processes.