Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2137548	11/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clear Sky Dermatology Llc	2620 N 140th Ave, Goodyear, 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 quality assessment (QA) policies and interview with the facility personnel, the laboratory failed to perform and document quality assessment activities. Findings include: 1. The laboratory performs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 264. 2. The laboratory's established policy titled, "Mohs Tissue Slide Quality Accuracy Check" states, "In an effort to assure quality of Mohs sections slides, every 50 cases a slide will be pulled at random and examined for proper labeling, specimen orientation, histologic staining, integrity of margins present, visibility of the margins, and technical qualities...A form will be filled out to include patient's name, surgery date, accession number, Mohs layer, and slide sectioning." 3. No documentation was presented for review to indicate the laboratory performed and documented the QA activity as indicated above from the time patient testing began in November 2017 through the date of the survey conducted on November 21, 2018. 4. The facility personnel confirmed that the laboratory did not have documentation of the QA review stated above.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials

	for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory began patient testing in November 2017 and processes and interprets histopathology slides from patient specimens during the Mohs process. The laboratory's approximate annual test volume is 264. 2. No documentation of the H & E stain acceptability was presented for review for testing that occurred on 06/20/2018. Approximately 1 patient was tested that day. 3. The facility personnel confirmed that the laboratory evaluated the H & E stain acceptability each day prior to testing patients but failed to document the stain acceptability on the date indicated above.