Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0975935	09/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Skin Specialists, Llc Dba	14537 W Indian School Rd, Ste 700, 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 accuracy checks presented for review for Mohs surgery slide reading for 2017 and 2018 and interview with the facility personnel, the laboratory failed to follow policies regarding the diagnostic comparison of the randomly selected cases read by the Mohs surgeon at the surveyed laboratory with that of another Mohs surgeon from an outside CLIA certified lab . Findings include: 1. Each case selected only included the pathology diagnosis not the Mohs diagnosis for the Mohs surgeon at the lab surveyed. Each comparative case indicated the Mohs diagnosis for the surgeon from the other CLIA certified lab. 2. None of the 23 diagnostic evaluations matched between the two surgeons since the diagnostic evaluations were for two different tests. 3. There was no documented comments or corrective actions supplied by the laboratory regarding the comparisons noted above. 4. The facility personnel acknowledged that the documented diagnostic evaluations between the two surgeons were not for the same test.
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 patient testing performed in the sub-specialty of histopathology for 1 out of 5 cases reviewed. Findings include: 1. No documentation of the H & E stain acceptability was presented for review for case number ZBG18-0004 from 03/01 /2018. 2. There were no entries at all on the log for 03/01/2018. The log included other criteria such as temperatures, microscope and cryostat maintenance duties. 4. The facility personnel acknowledged that the H& E stain acceptability for 03/01/2018 was mistakenly entered on the line for 02/29/2018 as were the other criteria. There was no patient testing performed on 02/29/2018.