Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0679853	03/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Specialized Gynecology, Llc	300 W Clarendon Ave Ste 100, Phoenix, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the laboratory director, the laboratory director failed to approve, sign and date the procedure manual before use. Findings include: 1. The laboratory began patient testing in the sub-specialty of Histopathology in June 2021, with a reported annual test volume of 233. 2. The procedure, "Procedure Manual for Anatomic Pathology" presented for review during the survey conducted on March 1, 2023 failed to include the approval, signature and date of the current laboratory director before use. 3. The laboratory director interviewed on March 1, 2023 at 12:50pm acknowledged that the procedure manual indicated above was not signed and dated by the current laboratory director at the time of the survey.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

	This STANDARD is not met as evidenced by: Based on lack of a microscope maintenance policy for review and interview with the laboratory director, the laboratory failed to establish a microscope maintenance policy that indicates specific routine maintenance procedures, as well as scheduled preventative maintenance procedures. Findings include: 1. No documentation was presented for review during the survey performed on March 1, 2023 to indicate the laboratory established a microscope maintenance policy, including routine and preventative maintenance. 2. The laboratory director interviewed on March 1, 2023 at 1:20pm acknowledged that no microscope maintenance policy was established by the laboratory. 3. The laboratory's annual test volume under the sub-specialty of Histopathology is approximately 233.
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 laboratory director, the laboratory failed to document the acceptability of staining materials used on patient specimens for testing performed in the sub-specialty of Histopathology. Findings include: 1. The laboratory began testing in the sub-specialty of Histopathology in June 2021, with an approximate annual test volume of 233. The laboratory collects and sends biopsy specimens to another CLIA-certified laboratory for processing. The processed specimens are mounted on a slide and stained with the Hematoxylin & Eosin (H&E) stain and then returned to the laboratory where the pathologist performs the reading/interpretation of the stained specimens and issues a diagnosis. 2. The laboratory's established policy states, "Quality control will be performed upon the glass slides at the time of review by the pathologist." 3. The laboratory failed to document the acceptability of the H&E staining materials each day of use for intended reactivity to ensure predictable staining characteristics from June 2021 through the date of the survey conducted on March 1, 2023. 4. The laboratory director interviewed on March 1, 2023 at 1:15pm confirmed that the laboratory failed to document the H&E stain acceptability from the date the laboratory began patient testing through the date of the survey, as indicated above.