Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2051762	10/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Affiliated Laboratories	21355 N 83rd St, Scottsdale, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for review and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2022. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation of Biopsy specimens at least twice annually during 2022. 2. The LD interviewed on 10/21/24 at 1:20 PM confirmed the laboratory failed to verify the accuracy of the testing indicated above at least twice annually during 2022. 3. The laboratory's reported annual test volume in the subspecialty of Histopathology is 7,500.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of positive and negative Quality Control (QC) documentation for Immunohistochemical (IHC) stains from 10/05/2022 through the date of the survey on 10/21/2024, review of patient test reports and interview with the laboratory director

	(LD), the laboratory failed to check IHC stains for positive and negative reactivity each time of use. Findings include: 1. The laboratory performs the microscopic interpretation of tissue specimens in the subspecialty of Histopathology, with a reported annual test volume of 7,500. 2. No documentation was provided for review to indicate the laboratory evaluated the positive and negative stain acceptability for each IHC stain performed on 8/14/2023 (case# E23-16237). 3. No documentation was presented for review during the survey to indicate the laboratory evaluated the positive and negative stain acceptability for each IHC stain performed for testing that occurred from 10/05/2022 through 10/21/2024. 4. The number of patient specimens tested with IHC stains during the timeframe indicated above could not be determined at the time of the survey. 5. The LD interviewed on 10/21/2024 at 1:30 PM confirmed the laboratory failed to check each IHC stain for positive and negative reactivity each time of use during the timeframe indicated above.