Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2168807	02/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Services Inc	1277 West 1650 S (Left) Villos Townhome, Cedar City, UT	

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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation, and interview with staff, the laboratory failed to retain histopathology slides at least 10 years from the date of examination for 10 of 10 histopathology cases reviewed for testing performed from June to August 2020. The laboratory performed approximately 300 tests per year. Findings include: 1. The laboratory patient test records review and e-mail interview with the laboratory director via email the laboratory did not retain slides for cases PWJ20: -4157,- 4355, -3114, -3529, -3962, -4351, -2576, -3020, 3481, and -2540. The slides were available for virtual review and the glass slide image was available virtually. 2. In an interivew conducted by email on 02/22/2021 the laboratory director stated the slides and virtual images were stored off-site at the Irvine, California laboratory location.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

	This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation, and interview with the director, the laboratory failed to have a written or electronic request for histopathology patient testing from an authorized person for 10 of 10 test records review. Findings include: 1. Patient test records review failed to include the written or electronic request from the referring dermatologist for histopathology diagnosis for 10 of 10 case records reviewed from June of 2020 to August 2020 (PWJ20: -4157,- 4355, -3114, -3529, -3962, -4351, -2576, -3020, 3481, and -2540) . 2. In an interview with the director via email on 02/22/2021 the director stated the test requisition was included in the test record sent for review. The test records sent included the test report that included the location where the specimen was referred but not the test request for each biopsy location, the patient, name, identification, age or date of birth, or diagnosis.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on test report review, lack of documentation and interview via email. the laboratory failed to include the location where gross analysis was performed for 10 of 10 test histopathology reports reviewed. The laboratory performs approximately 300 test per year. Findings include: 1. The test report review included a gross description including the size dimension in centimeters (cm) of the skin biopsies performed for 10 of 10 reports reviewed (PWJ20: -4157,- 4355, -3114, -3529, -3962, -4351, -2576, -3020, -3481, and -2540). 2. The test reports failed to state the performance location for gross analyses including only the location where professional component and technical components were performed. The report stated the professional component was performed at the Utah location. This is not correct for the gross analysis portion of the test. 3. In an interview via e-mail with the laboratory director on 02/22/2021 the director failed to answer the question concerning the location where gross analysis were performed. In a previous e-mail interview on about 02/05/2021 and in the laboratory procedure included and the director wrote the process was to log into the website for case selection, assign cases to themselves for review and diagnosis, then review the slides and the digital record for the case and report the results. The pathologist/dermatopathology may order re-cuts or special stains as needed. The system did not include gross analysis performance location.