Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2103543	01/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lumea	2889 West Ashton Blvd, Suite 300, Lehi, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to document stain reagent expiration dates for Eosin (E), Hematoxylin (H), peroxidase acid Schiff (PAS), H. pylori, CK20, and Cytokeratin. The laboratory performed approximately 8500 slide stains per year. Findings include: 1. Stain records reviewed failed to include the expiration dates of the stains used for histopathology cell diagnosis (H&E) and differential stain interpretation (PIN 4, CK20, H. pylori, and PAS) . 2. In an interview conducted on 01/21/2020 at approximately 1.15 P.M. staff confirmed they did not record stain expiration dates for histopathology stains in use.
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 histopathology test reports reviewed, lack of documentation, and interview with staff, the laboratory failed to include the statement that the laboratory test methods for histopathology core biopsy testing method was not FDA approved for 2 of 1Histopathology test reports reviewed. Findings include: 1. Histopathology report for specimen LMP 18-0404 Histopathology Hematoxylin and Eosin stain collected on 04/17/2018 and TxB 18-14 collected on 06/20/2018 that included PIN 4 immunohisotchemical stains failed to include the statement that the LUMEA core biopsy test method was not FDA approved, ("The performance characteristics of this test were determined by the (Laboratory Name). It has not been cleared or approved by the US Food and Drug Administration.") 2. In an interview conducted on 01/21 /2020 with the laboratory general supervisor and director, the staff confirmed the test reports did not include the FDA disclaimer.