Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2103543	02/06/2018
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
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 quality control records review, Immunohistochemical (IHC) Stain records review, and interview with staff, the laboratory failed to document they checked PIN 4 IHC stains for positive and negative reactivity each time of use for 6 of 6 PIN 4 stain group specimens reviewed for testing performed from 06/30/2016 to 01/26/2018. Findings include: 1. IHC stain records review for Patient specimen LMD16-592 collected on 06/30/2016; LMD17-029 on 01/10/2017; LMD17-225 on 02/09/2017; LMD17-694 on 08/28/2017; LMD17-997 on 12/08/2017; and LMD18-119 on 01/26/2018, failed to include documentation a quality control specimen was checked for positive and negative reactivity for the 4 stains used in the PIN 4 stain group, (markers for CK 5, CK 14, p63, and p504). 2. In an interview with staff conducted on 02/06/2018 at approximately 6:15 P.M. staff confirmed they did not provide quality control slides for each specimen or batch of slides stained using the IHC PIN 4 stain group.
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 patient test reports review, lack of documentation, and confirmation by the director, the laboratory failed to include on histopathology test reports information used to interpret Immunohistochemical (IHC) stain tests results for approximately 6 of 6 histopathology tests reports reviewed. Findings include: 1. Patient test reports reviewed for IHC stains for Patient specimens: LMD16-592 collected on 06/30/2016; LMD17-029 on 01/10/2017; LMD17-225 on 02/09/2017; LMD17-694 on 08/28/2017; LMD17-997 on 12/08/2017; and LMD18-119 on 01/26/2018, failed to include information stating: "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration" to provide accurate test interpretation by the user of test results. 2. In an interview conducted on 02/06/2018 at approximately 6:25 P.M. staff confirmed they had not been consistent in providing the disclaimer information on test reports for PIN 4 complex stained biopsies.