Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2248858	(X3) Date Survey Completed 10/25/2023
Name of Provider or Supplier Kfhp Skyline Mohs Laboratory	**Street Address, City, State** 1375 E 20th Ave, Denver, CO	

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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the Laboratory Director (LD) failed to provide an approved procedure manual for personnel to reference during all aspects of the histopathology testing process (refer to D6106), and failed to ensure the establishment and implementation of preanalytic, analytic, and postanalytic Quality Assessment (QA) plans for histopathology (refer to D6094). The laboratory performs approximately 2,000 histopathology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and interviews with the Mohs technician (not included on CMS Form 209) and General Supervisor (GS), the Laboratory Director (LD), failed to ensure that the quality assessment (QA) programs for general laboratory systems, as well as preanalytic, analytic, and postanalytic QA programs for histopathology testing are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as

	they occur since testing began in March 2022. The laboratory performs approximately 2,000 histopathology tests annually. Findings include: 1. Based on a lack of general laboratory QA programs, and preanalytic, analytic, and postanalytic QA programs for histopathology in the laboratory's policies and procedures manual, the LD failed to ensure that the quality assessment (QA) programs for general laboratory systems, as well as preanalytic, analytic, and postanalytic QA programs for histopathology testing are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur since testing began in March 2022. 2. Based on an interview with the Mohs technician (not included on CMS Form 209), and the GS, at approximately 2:30 PM, and 3:00 PM, respectively, confirmed that the LD failed to ensure that the quality assessment (QA) programs for general laboratory systems, as well as preanalytic, analytic, and postanalytic QA programs for histopathology testing are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur since testing began in March 2022.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and an interview with a Mohs technician (not included on CMS Form 209), the laboratory director failed to provide an approved procedure manual for the laboratory's Skyline location for personnel to reference during all aspects of the histopathology testing process since testing began in March of 2022. The laboratory performs approximately 2,000 histopathology tests a year. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory director failed to provide an approved procedure manual for personnel to reference during all aspects of histopathology testing at the Skyline location. 2. An interview with a Mohs technician (not included on CMS Form 209), at approximately 2:30 PM confirmed the laboratory was using a seperate laboratory's procedure manual, and that the laboratory director failed provide an approved procedure manual for personnel to reference during all aspects of the histopathology testing process at the Skyline location.