

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2054758	(X3) Date Survey Completed 03/25/2022
Name of Provider or Supplier Mohs Micrographic Surgery Laboratory	Street Address, City, State 3140 Kearney St, Bldg 2, 2nd Fl, Fremont, CA	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patients test records, checking of the solution used in patient testing and interview with the laboratory staff on March 25, 2022, at 11:50 am, the laboratory used expired KOH solution in patient testing. The findings include: 1. The laboratory performed fungal test on 3/14/2022 on 2 patients' samples in which it used expired KOH solution. The used KOH solution was expired on 2/28/2022. The test results of both patients were negative. Since the laboratory used an expired solution to test patients' sample, therefore, the accuracy of the reported negative results can not be assured. 2. The laboratory staff on March 25, 2022, at 11:50 am, affirmed that the laboratory used an expired KOH solution to test patients' sample. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/25/2022, stated that the laboratory performs approximately 125 tests, annually.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel</p>

meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's patients test records, checking of the solution used in patient testing and interview with the laboratory staff on March 25, 2022, at 11:50 am, the laboratory director failed to ensure the laboratory's compliance with the CLIA regulations. The findings include: See D5417.