

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1030501	<b>(X3) Date Survey Completed</b>  04/14/2022
<b>Name of Provider or Supplier</b>  Md Solutions Medical Corporation	<b>Street Address, City, State</b>  15477 Ventura Blvd Ste 100, Sherman Oaks, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3043</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of an up-to-date policies and procedures manual, policy for documents, reports, and Mohs slides retention, review of six (6) randomly chosen dermatopathology test records, and interview with the laboratory's staff (LS), the laboratory failed to have a policy for documents and Mohs procedure slides retention. The findings included: 1. On the day of survey, April 14, 2022, at approximately 1:00 p.m. based on review of the policies and procedures (P&amp;P) manual, the laboratory failed to provide an up-to-date P&amp;P on the current practice including a policy for length of retention of documents, patient reports, and Mohs slides. 2. The laboratory LS confirmed by interview on April 14, 2022, at approximately 1:15 p.m. that the laboratory did not have an updated P&amp;P for documents retention and Mohs slide preparations retention policies. 3. The laboratory reports performing approximately 1,430 Mohs dermatopathology patients' tests results annually.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

	<p>Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory's reagent materials and interview with the laboratory's staff (LS); it was determined that the laboratory failed to label reagents to indicate the opening, preparation, and expiration dates when such reagents are used. The findings included: 1. Based on the surveyor's observation during the laboratory tour on April 14, 2022, at approximately 11:45 a.m., the LS indicated that no opening, preparation, or expiration date labels were documented for all the reagents used in the laboratory. 2. The laboratory's LS affirmed in an interview conducted April 14, 2022, at approximately 11:45 a.m. that the reagents currently used to mark Mohs processed patients' samples were not labeled with opening, preparation, and expiration dates. (Yellow, blue and green marker dyes). 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 1,430 patients' samples annually</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 the surveyors' observation, examination of laboratory reagents, and interview with the laboratory staff (LS), it was determined that the laboratory failed to not use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, April 14, 2022, at approximately 11:50 a.m. the surveyor found the following reagents being used beyond its expiration date: a) Red Margin Marker Lot #31373 Expired 7/2016 b) Optical Wound 1 Lot# 591977 Expired 6/2019 2. The LS affirmed on 4/14/2022 at approximately 11:45 a.m. testing personnel using reagents beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately 1,430 samples annually.</p>
<p><b>D6082</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records of policies and procedures, lack of reagent labelling, use of expired reagents, and interview with the laboratory staff on April 14, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytical and analytic phases of laboratory testing were monitored. D3043, See D5415, and D5417.</p>