

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1031513	<b>(X3) Date Survey Completed</b>  09/08/2023
<b>Name of Provider or Supplier</b>  Mohs Surgery Specialists Llc	<b>Street Address, City, State</b>  4950 Essen Lane, Suite 301, Baton Rouge, LA	
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>D0000</b>	A Certification survey was performed on September 8, 2023 at Mohs Surgery Specialists, LLC, CLIA ID 19D1031513. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<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) 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 by surveyor and interview with personnel, the laboratory failed to label marking dyes stored in secondary containers with the identity, expiration date, and applicable storage information. Findings: 1. Observation by surveyor during the laboratory tour on September 8, 2023 at 9:30 am revealed the laboratory stored smaller bottles of marking dyes in four (4) procedure rooms. 2. In interview on September 8, 2023 at 9:48 am, Histotech #1 stated the smaller bottles of marking dyes were filled from larger (master) bottles located in another room. 3. Further observation by surveyor during the laboratory tour revealed the smaller bottles of marking dyes were not labeled with the lot, expiration dates, and applicable information of the master bottles. 4. In further interview on September 8, 2023 at 9:48 am, Histotech #1 confirmed the smaller marking dyes were not labeled with the master marking dye bottle's information.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</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.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of policies, quality assessment records, and interview with personnel, the laboratory failed to ensure marking dyes did not exceed their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on September 8, 2023 at 9:30 am revealed the following expired items: a) Stat Lab Blue Margin Marker, Lot 39834, Expiration date: 3/2017, Quantity: One (1) bottle b) Cancer Diagnostics, CDI, Blue tissue marking dye, Lot 21069, Expiration date: 2023-03-31, Quantity: one (1) bottle c) Cancer Diagnostics, CDI, Red tissue marking dye, Lot 9094, Expiration date: 2021-04-01, Quantity: one (1) bottle d) Cancer Diagnostics, CDI, Black tissue marking dye, Lot 9150, Expiration date: 2021-05-01, Quantity: two (2) bottles 2. Review of the laboratory's "Mohs Statement of Policy and Procedure" under the "Quality Control" section revealed "All reagents are used within the expiration date. Expired reagents are discarded." 3. Review of the laboratory's "Monthly Internal QA" revealed the laboratory performs a monthly check for "expired chemicals". 4. In interview on September 8, 2023 at 9:48 am, Histotech #1 stated the laboratory checks for expired chemicals monthly, which did not include the marking dyes as they did not consider those to be laboratory related supplies. Histotech # 1 confirmed the identified items were expired.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation by surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to label marking dyes stored in secondary containers with the identity, expiration date, and applicable storage information. Refer to D5415. 2. The laboratory failed to ensure marking dyes did not exceed their expiration dates. Refer to D5417.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to include written description of duties and responsibilities of personnel involved in all phases of testing. Findings: 1. Review of the laboratory's documents and personnel records revealed the laboratory did not have written job responsibilities for the following: Laboratory Director Clinical Consultant Technical Supervisor General Supervisor Testing Personnel 2. In interview on September 8, 2023 at 10:48 am, Histotech # 1 confirmed the laboratory did not have written job descriptions for the identified roles that the Laboratory Director serves as.