

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2086344	(X3) Date Survey Completed 12/16/2020
Name of Provider or Supplier Larkin Mohs Laboratory	Street Address, City, State 6140 Sw 70 St, 2nd Fl, South Miami, FL	
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
D0000	A recertification survey was completed on 12/14/2020 to 12/16/2020 at LARKIN MOHS LABORATORY. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview , the laboratory failed to provide documentation of MOHS tissue mapping for patients S18-14060 and 19-004 onsite. Findings Included : Review of Patient Reports revealed MOHS maps were missing from S18-14060 and 19-004 patient records . During an interview conducted on 12/14/2020 at 1: 54pm , the laboratory consultant confirmed no documentation of MOHS map for tissue mapping for patient S18-14060 and 19-004 onsite.</p>
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 observation and interview , the laboratory failed to have dyes , reagent alcohol and liquid submount that were not expired onsite. Findings Included:</p>

Observation of the laboratory revealed red, blue, yellow and black dye inks expiring after 9-01-2020 on the counter. A biohazard cabinet contained liquid submount and reagent alcohol that expired after 9-30-19. During an interview conducted on 12/14 /2020 at 1:54pm , the laboratory consultant confirmed dyes , reagent alcohol and liquid submount were expired onsite .