

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2077425	<b>(X3) Date Survey Completed</b>  07/12/2018
<b>Name of Provider or Supplier</b>  Dermatology Specialists Of Brighton	<b>Street Address, City, State</b>  2305 Genoa Business Park Dr, Suite 180, Brighton, MI	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to verify the accuracy of testing for the Mohs' tissue slide examination at least twice annually for one (1st half of 2018) of two years reviewed. Findings include: 1. On July 12, 2018 at 2:50 PM, record review for the verification of accuracy of the Mohs' tissue slide examination revealed there was no documentation for one (1st half of 2018) of two years reviewed. When queried, the office manager was not able to provide documentation to show the verification of accuracy was completed. 2. During the interview on July 12, 2018 at 2:50 PM, the office manager confirmed the verification or accuracy was not documented for the 1st half of 2018.</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) 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 and interview, the laboratory failed to label the Mohs' tissue</p>

	<p>marking dyes (blue, red, and yellow) with the contents, storage requirements, preparation, and expiration dates for the poured off inks stored in formalin containers. Findings include: 1. On July 12, 2018 at 1:05 PM during a tour of the laboratory, the surveyor observed the Mohs' tissue marking dyes (blue, red, and yellow) poured off into formalin containers. There was no documentation on the containers with the contents, storage requirements, preparation, or expiration dates when the dyes were put into use. 2. During the interview on July 12, 2018 at 1:05 PM, the office manager confirmed the poured off marking dye containers were no labeled.</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 observation and interview, the laboratory failed to use the Mohs' tissue marking dye (yellow dye) before the manufacturer's expiration date. Findings include: 1. During a tour of the laboratory on July 12, 2018 at 1:05 PM, the surveyor observed the yellow tissue marking dye used for the Mohs' testing with an expiration date of May 2018 recorded on the manufacturer's label. 2. During the interview on July 12, 2018 at 1:05 PM, the office manager confirmed the Mohs' yellow tissue marking dye was used past the manufacturer's stated expiration date.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic laboratory systems for one (1st half of 2018) of three twice a year assessments reviewed in 2016 to 2018. Findings include: 1. On July 12, 2018 at 2:58 PM, record review of the twice a year "Quality Assurance Checklist" revealed there was no documentation for one (1st half of 2018) of three twice a year assessments reviewed. 2. When queried on July 12, 2018 at 2:58 PM, the office manager was unable to provide the surveyor with the documentation requested. 3. During the interview on July 12, 2018 at 2:58 PM, the office manager confirmed the "Quality Assurance Checklist" was not performed and documented in the 1st half of 2018.</p>
<p><b>D5803</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p>

This STANDARD is not met as evidenced by:

. Based on document review and interview, the laboratory failed to have the final Mohs' map maintained as part of the patient's electronic medical record (EMR) for one (#3) of ten patient charts reviewed. Findings include: 1. On July 12, 2018 at 2:30 PM, document review for one (#3) of ten patient charts reviewed revealed the final Mohs' map was not maintained in the patient's EMR. 2. During the interview on July 12, 2018 at 2:30 PM, the office manager confirmed the Mohs' map was not maintained in the patient's EMR and was unavailable on the day of the survey.