

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0692358	(X3) Date Survey Completed 10/03/2018
Name of Provider or Supplier Midwest Center For Dermatology & Pathology - I & D	Street Address, City, State 43900 Garfield Road Suite 228, Clinton Township, MI	
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
D5415	<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 mineral oil pour-off bottle with the preparation and expiration date on the day of the survey. Findings include: 1. On October 3, 2018 at 11:45 AM, during a tour of the laboratory, the surveyor observed a large mineral oil bottle and a smaller pour-off bottle in use that did not have documentation of a preparation and expiration date on the label. 2. During the interview on October 3, 2018 at 11:45 AM, technical supervisor #2 as listed on the CMS-209 confirmed the smaller mineral oil pour-off bottle did not have a preparation and expiration date on the label.</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, record review, and interview, the laboratory failed to use the</p>

mycology potassium hydroxide (KOH) 20% reagent before the manufacturer's expiration date for two (September 2016 to September 2018) of two years of use and for three (#19-#21) of 21 patient charts audited. Findings include: 1. During a tour of the laboratory on October 3, 2018 at 11:45 AM, the surveyor observed KOH 20% in use with an expiration date of April 2014 recorded on the manufacturer's label. 2. On October 3, 2018 at approximately 12:15 PM, record review revealed for two (September 2016 to September 2018) of two years and for three (#19-#21) of 21 patient charts audited, the KOH 20% was expired. 3. During the interview on October 3, 2018 at 12:15 PM, technical supervisor #2 as listed on the CMS-209 confirmed the KOH reagent was used past the manufacturer's stated expiration date.