

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0681911	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier South Bend Clinic Ironwood Dermatology	Street Address, City, State 2102 E Inwood Rd, South Bend, IN	
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
D5217	<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 twice annually (2nd verification) the accuracy of its Mohs Surgery slides for 2020 and three (PT#1 - PT#3) of nine patients reviewed with testing in 2020. Findings include: 1. On 12/15 /2021 at 10:24 am, upon request for 2020 Mohs twice-annual verification for proficiency testing, SP1 confirmed that the laboratory had verification documentation for only one of two verifications in 2020. 2. Review of the laboratory's policy, "Protocol for Proficiency Testing", no signature or approval date by laboratory director, indicated that proficiency slides are submitted to an outside laboratory twice a year. 3. Review of nine medical records indicated that the following patients had Mohs surgery performed in 2020 without a second verification to assure the accuracy of the Mohs Surgery performed. PT#1 on 7/7/2020 PT#2 on 8/11/2020 PT#3 on 9/3 /2020 4. The annual test volume for Mohs testing is approximately 1200.</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, one of two stains (Eosin) for</p>

Mohs Surgery was used past the expiration date (January 8, 2020) for eight of nine patients (PT#1 to PT #8) reviewed. Findings include: 1. On 12/15/21 at 11:39 am, one of one staining bottles (Eosin lot number 010818) was observed to have an expiration date of 1/8/2020 and an open date of 1/26/2018. 2. On 12/15/21 at 11:40 am, SP1 confirmed Eosin lot number 010818 was currently in use for PT testing. 3. Review of nine medical records indicated that the samples from PT#1 through PT#8 for Mohs surgery had been stained with the Eosin lot number 010818. PT#1 on 7/7/2020 PT#2 on 8/11/2020 PT#3 on 9/3/2020 PT#4 on 1/12/2021 PT#5 on 2/11/2021 PT#6 on 3/9/2021 PT#7 on 8/19/2021 PT#8 on 9/14/2021 4. The annual test volume for histopathology testing is approximately 1200.