

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0933599	<b>(X3) Date Survey Completed</b>  11/17/2020
<b>Name of Provider or Supplier</b>  St Luke's Clinic - Dermatology Wood River	<b>Street Address, City, State</b>  100 Hospital Dr Ste 201, Ketchum, ID	
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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on a random review of Mohs patient slides and interview with the laboratory histotechnician on 11/17/2020, the laboratory failed to follow written policies and procedures for specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. The findings include: 1. Based on a random review of Mohs patient slides from April 2018 through June 2020, patient A from 1/3/2019 on the Mohs log, with case number 19-005 had four (4) slides listed in the log. The histotechnician pulled the slides for case number 19-005 and slide number four was labeled with case number 19-005, 1/3/2019, stage I, 1-4 and patient B's name. Patient B was on the line below patient A in the Mohs log and listed as case number 19-006. 2. The histotechnician then pulled the Mohs slides for patient B, case number 19-006. The Mohs log showed that patient B, case number 19-006, had eight (8) slides, the histotechnician was only able to retrieve seven (7) slides with patient B's name and case number 19-006 from 1/3/2019. 3. An interview with the histotechnician on 11/17/2020 at 12:30 pm, confirmed that these were the only slides for patients A and B for 1/03/2019 case numbers 19-005 and 19-006 respectively. 4. There were three (3) Mohs procedures performed on 1/3/2019 and the laboratory reports performing 100 Mohs procedures annually.</p>
<b>D5417</b>	<b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b>

CFR(s): 493.1252(d)

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 direct observation and an interview with the laboratory director on 11/17/2020, the laboratory failed to discontinue use of reagents, solutions, culture media, control materials, calibration materials, and other supplies that have exceeded their expiration date, have deteriorated, or are of substandard quality. The findings include: 1. The laboratory has two microscopes for potassium hydroxide (KOH) testing and at each microscope one bottle of testing reagent, 10% potassium hydroxide, is stored. Based on direct observation, both locations had a bottle of 10% potassium hydroxide with lot number 451533 that expired on 8/21/2020. 2. An interview with the laboratory director on 11/17/2020 at 12:40 pm confirmed that the expired 10% potassium hydroxide was being used for patient testing. 3. The laboratory reports performing 50 KOH tests annually.

**D5603**

**HISTOPATHOLOGY**

CFR(s): 493.1273(b)(f)

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a random review of Mohs patient slides and interview with the laboratory histotechnician on 11/17/2020, the laboratory failed to retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). The findings include: 1. The histotechnician pulled slides for patient B, case number 19-006, listed in the Mohs log on 1/3/2019. The log listed that there were eight (8) slides for case 19-006. The histotechnician was only able to retrieve seven (7) slides for this case number. See D5311 2. An interview with the histotechnician on 11/17/2020 at 12:30 pm, confirmed that these, seven (7) slides, were the only slides for case 19-006, patient B on 1/3/2019. 3. There were three (3) Mohs procedures performed on 1/3/19 and the laboratory reports performing 100 Mohs procedures annually.