

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2188636	<b>(X3) Date Survey Completed</b> 06/29/2021
<b>Name of Provider or Supplier</b> Ogden Clinic West Point	<b>Street Address, City, State</b> 2973 W 125 S, West Point, UT	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on Standard Operating Procedure (SOP) review, documentation review, and interview with histotech, SOPs are not being followed as written. Findings include: 1. SOP for cryostat maintenance includes instructions to thaw and decontaminate the cryostat quarterly. Maintenance record review does not include quarterly thaw and decontamination. 2. Quality Assurance (QA) SOP states that a comparison review of 5 or more Mohs cases will be performed twice annually. QA log states 3-5 Mohs cases will be reviewed twice annually. QA log review includes review of 3-5 Mohs cases twice annually. 3. SOP for cryosectioning states cryostat temperature acceptable range is -20 to -25 C. SOP for equipment states cryostat temperature acceptable range is -20 to -30C. SOP for frozen biopsy states acceptable cryostat temperature range is -23 to -28C. Cryostat maintenance log states cryostat acceptable temperature is -24 to -30C. 4. In an interview o 6/29/21 at approximately 3:00 pm, the histotech confirmed that actual practice does not match what is written in the SOP manual.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)</p>

Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview with histotech, the laboratory location where Mohs testing was performed is incorrect on the Mohs map, which is part of the patient test report. Findings include: 1. In 7 of 7 patient records reviewed, the laboratory location on the Mohs map included an incorrect address. 2. In an interview on 6/29/21 at approximately 3:00 pm, the histotech confirmed that the address on the Mohs map was the address of the Ogden Clinic Bountiful location.