

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2088704	(X3) Date Survey Completed 06/29/2021
Name of Provider or Supplier Ogden Clinic - Bountiful	Street Address, City, State 1560 Renaissance Town Dr Ste 210, Bountiful, UT	
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
D5401	<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 on 6/29/21 at approximately 12:30 pm, the histotech confirmed that actual practice does not match the written SOPs.</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>

This STANDARD is not met as evidenced by:

Based on direct observation and interview with histotech, reagents and supplies were used after their expiration date. Findings include: 1. Three bottles of acetone were found in a cabinet, two full and one currently in use. The expiration date on all three bottles was 3/31/21. 2. Formalin jars for use in sending tissue to a reference laboratory were found in the supply cabinet. The expiration date on the formalin jars was 9/20. 3. Permanent Red stain was found in the refrigerator with an expiration date of 5/31/21. 4. Hi-Def reagent was found in the refrigerator with an expiration date of 12/31/20. 5. In an interview on 6/29/21 at approximately 12:45 pm, the histotech confirmed that expired reagents were in use.