

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2088704	(X3) Date Survey Completed 10/09/2018
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
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 Mohs maps review, lack of documentation, and interview with staff, the laboratory failed to include the lot numbers and expiration dates for 2 of 2 immunohistochemical test kit staining systems in use from 10/09/2016 to 10/09/2018 in the laboratory test records to ensure test kits were not used past their expiration dates. The laboratory tests approximately 15 cases per year for the persistence or absence of pathogenic melanocytes. Findings include: 1. Mohs surgery maps review for 2 cases selected, MH17-894 stained on 07/10/2017 and MH18-145 stained on 01/31/2018, included documentation the laboratory performed Mart 1 and SOX 10 immunohistochemical stains to aid in determination of the presence of melanocytes in the layered specimens collected. 2. The laboratory lacked documentation the lot number of stains used on the test dates were not in use past the kit expiration date. 3. In an interview with staff on 10/09/2018 at approximately 11:30 A.M. staff confirmed they did not have a record for each lot number and expiration date for Mart 1 and SOX 10 stain kits.</p>
D5607	<p>HISTOPATHOLOGY CFR(s): 493.1273(d)(f)</p> <p>(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. (f) The laboratory must document</p>

all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on histopathology fixed tissue biopsy reports review, lack of documentation, and interview with staff, the tissue pathology reports for 4 of 4 reports reviewed failed to include the signature or electronic signature of the individual qualified to report histopathology tissue biopsy specimens. The laboratory performs approximately 125 fixed tissue biopsy diagnoses per year. Findings include: 1. Histopathology formalin fixed tissue reports reviewed for biopsy specimens T16-01184, T16-001258, T17-000204, and T18-000411 lacked the signature or electronic signature of the dermatologist qualified to make the histopathology diagnoses. 2. In an interview conducted on 10/09/2018 at approximately 11:45 A.M. staff stated the reports were dictated by the physician without an electronic or hand written signature.