

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0699048	(X3) Date Survey Completed 08/28/2018
Name of Provider or Supplier Daniel J Hansen, Do, Pllc	Street Address, City, State 1495 E Ridgeline Dr, Ogden, 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
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, patient test record review, and interview with staff, the laboratory failed to ensure patient histopathology test reports were transcribed from dictation of the tests results to the patient's chart record in a timely manner for 5 of 8 biopsy specimens reviewed from 08/31/2016 to 07/27/2018. Findings include: 1. Patient histopathology test reports for biopsy specimens collected on 12/20/2016 for patient date of birth (DOB) 08/14/1922, on 08/24/2017 for patient DOB 10/02/1978, on 05/02/2018 for patient DOB 09/02/1935; and on 07/27/2018 for patient DOB 12/23 /1941 did not have a written report for the microscopic analysis that included the specimen number, microscopic analysis, gross analysis and signature of the qualified testing person. 2. In an interview with the laboratory staff on 08/28/2018 at approximately 5:30 P. M. staff stated the laboratory process was to: 1. Record the specimen into the laboratory log book, 2. Send the specimen for processing into a permanently mounted and stained slide, 3. The dermatologist reviewed the slide and dictated the test results for a written report; 4. Record the diagnosis into the log book and notify the patient. Staff confirmed the laboratory was behind their turnaround time for recording test results into the patients chart record.</p>

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on patient test reports review and interview with staff, the laboratory failed to monitor test reports to monitor for accuracy for 1 of 5 Mohs surgical reports stating the specimen collected contained No residual tumor with clear margins at stage I of a three stage procedure for case 18M-180. Findings include: 1. The laboratory failed to document a review patient surgical test reports for errors in reporting by multiple choice selections in the laboratory information system for findings reported for each stage of micrographic horizontal frozen section removal of tumor cells. 2. Patient chart report for case 18M-180 included for stage I of a stage III procedure that stage I reported residual tumor - margins clear when residual tumor was present and the map showed margins were not clear, the process continued to stage II with residual tumor - margins clear, and at state III No residual tumor was present and reported as such. Mohs map included tumor with positive margins at stages I and II. 3. In an interview with staff on 08/28/2018 at approximately 5:30 P.M. staff confirmed the surgical report did not reflect the map results.