

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2104679	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Integra Dermatology, Pa	Street Address, City, State 5725 Loftus Lane, Savage, MN	
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
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to document the time patient specimens were received into the laboratory. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a tour of the laboratory on 01/30/18 at 1:10 p.m. 2. Requirements for documentation of patient specimen (tissue) receipt time into the laboratory were not found in the CLIA Laboratory Manual. 3. The time of tissue receipt into the laboratory was not documented in testing records for 2 cases reviewed on date of survey. 4. In an interview on 01/30/18 at 3:00 p.m., the MT confirmed the above finding and stated the time tissue was received into the laboratory never been documented.</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> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure Histopathology testing material was not used after the expiration date had been exceeded. Findings are as follows: 1. The laboratory</p>

performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a tour of the laboratory on 01/30/18 at 1:10 p.m. 2. Expired tissue marking materials were observed as present and available for use during the tour of the laboratory. See below. -StatLab Yellow Margin Marker Lot 41510 Expiration 09/17 -Avantik Tissue Marking Dye, Black Lot 39067 Expiration 04/17 -Avantik Tissue Marking Dye, Green Lot 41219 Expiration 08/17 -StatLab Red Margin Marker Lot 42610 Expiration 10/17 3. In an interview on 01/30/18 at 1:15 p.m., the MT confirmed the above materials were used after the expiration date had been exceeded.

D5609

HISTOPATHOLOGY
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to consistently document daily quality control (QC) activities for Histopathology staining procedures. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a tour of the laboratory on 01/30/18 at 1:10 p.m. 2. Daily QC performance with the first case of the testing day was established in the Hematoxylin and Eosin Staining Protocol found in the CLIA Laboratory Manual. 3. The laboratory failed to document the quality check for nuclei and cytoplasm color, quality determination and surgeon's initials on the following days of patient testing. Date Patients tested 10/31/17 4 11/14/17 3 11/21/17 5 11/28/17 2 12/14/17 6 12/19/17 2 01/11/18 3 01/18/18 3 QC records from October - December 2016 and October - December 2017 were reviewed on day of survey. No further instances of missing QC documentation was found. 4. In an interview on 01/30/18 at 3:00 p.m., the MT confirmed the above finding.