

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2096462	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier Us Dermatology Partners North Dallas	Street Address, City, State 5310 Harvest Hill Rd Ste 130, Dallas, TX	
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
D0000	An entrance conference was held 11/19/2019 with the Histotechnician and Regional Clinical Manager. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted on 11/19/2019, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1219 Histopathology 493.1441 Laboratories performing high complexity testing; laboratory director An exit conference was held on 11/19/2019 with the Histotechnician and Regional Clinical Manager. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5028	<p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policy, Quality Control (QC) logs and confirmed in interview the laboratory failed to meet the requirements for the specialty of histopathology as evidenced by: 1. The laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 2 of 6 days in 2018 (11 /2018) and 1 of 4 days in 2019 (07/2019). Refer to D5473, II.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper</p>

storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on direct observation, manufacturer's instructions, and staff interview, the laboratory failed to ensure the proper storage conditions were maintained for potassium hydroxide (KOH) reagents for 11 of 11 months in 2019. Findings: 1. Review of manufacturer's safety data sheets for KOH 10% reagent revealed: "7 Handling and storage ... Requirements to be met by storerooms and receptacles: 15 - 30 C" 2. During a tour of the laboratory on 11/19/2019 at 11:43 am, the following were observed stored in the storage room in the storage closet across from the laboratory: 2 bottles of Potassium Hydroxide 10%, lot #9255, expiration date 09/21 /2021 3. During an interview on 11/19/2019 at 11:43 am, the histotechnician was asked if the temperature was monitored and documented in the storage closet and she stated no, confirming the above findings. The laboratory failed to ensure the proper storage conditions were maintained for KOH reagents.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, cryostat maintenance logs, and confirmed in interview, the laboratory failed to perform the daily maintenance on cryostat A for 1 of 5 days in 2018 (11/2018). Findings: 1. Review of "QUALITY ASSURANCE MANUAL" laboratory policy revealed: "EQUIPMENT QUALITY CONTROL-CRYOSTAT 1. Temperature is recorded daily and documented. 2. Temperature range is -25C to -35C. 3. Corrective action is taken and documented if the temperature exceeds range. 4. Defrost of machine is done on a routine cycle at midnight each night. Defrosting is done periodically if needed for frost build up. 5. Interior is cleaned daily after use using alcohol, while wearing gloves. 6. Cryostat knives are disposable and are changed as needed ... 13. Every action is documented on the maintenance record form." 2. Review of cryostat maintenance log in 2018 revealed: 11 /08/2018 Daily cleaning and changing of blade was not performed The bottom of the log stated: "Clean: Daily on Mohs surgical days New blade: Daily on Mohs surgical days" The laboratory failed to perform the daily maintenance on a Mohs surgical day. 3. During the exit interview on 11/19/2019 at 12:30 pm, the histotechnician confirmed the above findings.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials

for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's procedure manual, Quality Control (QC) logs and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 4 of 4 days in 2018 (random review 11/2018) and 3 of 3 days in 2019 (random review 07/2019). Findings: 1. Review of H&E Staining laboratory policy revealed: "Principle ... Staining carried out on microscopic sections includes routine staining, which does a little more than differentiate between the nucleus and cytoplasm and special staining, which involves a multiple of special techniques to demonstrate one particular element to the exclusion of all others. The simplest staining is nuclear staining, and the stain most frequently used is hematoxylin. Eosin is the most widely used counterstaining routine on the sections. Used properly, at least three shades of pink can be obtained with eosin alone. Erythrocytes, collagen, and the cytoplasm of muscle or epithelial cells should stain with different shades of intensities of pink ... Quality Control ... There is a daily log sheet for the stain line that is to be completed each day" 2. A random review of the "Slide Quality & Maintenance" log in 2018 and 2019 revealed the following: The log had a column for "Stain Quality" and each day QC was documented with a checkmark in the column and the initials the laboratory director in another column. The log did not specify the meaning of the checkmark. The following dates were observed to be documented with a checkmark: November 2018: 5, 13, 20, 21 July 2019: 1, 16, 30 The laboratory failed to document the staining characteristics for the H&E stain. 3. During the exit interview on 11/19/2019 at 12:30 pm, the histotechnician confirmed the above findings. II. Based on review of laboratory policy, Quality Control (QC) logs and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 2 of 6 days in 2018 (11/2018) and 1 of 4 days in 2019 (07/2019). Findings: 1. Review of H&E Staining laboratory policy revealed: "Principle ... Staining carried out on microscopic sections includes routine staining, which does a little more than differentiate between the nucleus and cytoplasm and special staining, which involves a multiple of special techniques to demonstrate one particular element to the exclusion of all others. The simplest staining is nuclear staining, and the stain most frequently used is hematoxylin. Eosin is the most widely used counterstaining routine on the sections. Used properly, at least three shades of pink can be obtained with eosin alone. Erythrocytes, collagen, and the cytoplasm of muscle or epithelial cells should stain with different shades of intensities of pink ... Quality Control ... There is a daily log sheet for the stain line that is to be completed each day" 2. Review of the "Slide Quality & Maintenance" log in 2018 and 2019 revealed the following: The log had a column for "Stain Quality" and each day QC was documented with a checkmark in the column and the initials the laboratory director in another column. The log did not specify the meaning of the checkmark. The bottom of the log stated "H&E stain and section quality should be completed daily by the physician." The laboratory failed to document intended reactivity of the H&E stain on the following dates patients were tested in 2018 and 2019: 11/06/2018 Patient IDs: PM18-049, PM18-050, PM18-051, PM18-052, PM18-053, PM18-054 11/08/2018 Patient IDs: PM18-055, PM18-056, PM18-057, PM18-058, PM18-059, PM18-060, PM18-061 07/02/2019 Patient IDs: PM19-108, PM19-110, PM19-111, PM19-112, PM19-113 The laboratory failed to

document the staining characteristics for the H&E stain for each day of use. 3. During the exit interview on 11/19/2019 at 12:30 pm, the histotechnician confirmed the above findings. This was a repeat deficiency from a recertification survey on 11/07/2017.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, personnel files and confirmed in interview the technical consultant failed to evaluate and document the performance 1 of 3 Testing Persons (TP-3) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of "QUALITY ASSURANCE MANUAL" laboratory policy revealed: "TECHNICAL CONSULTANT The Technical Consultant is responsible for the technical and scientific oversight of the laboratory. The following represent the duties of the Technical Consultant ... 8. Evaluate and document the performance of individuals responsible for high complexity testing at least semi-annually during the first year the individual test patient specimens. Thereafter, evaluations must be performed at least annually. The Laboratory Director also performs this function." 2. Review of personnel records revealed TP-3 revealed a hire date of 09/11/2018. There were no records of initial training or semiannual competency performed by the technical consultant. 3. During an interview on 11/19/2019 at 10:05 am, the regional clinical manager stated she was unaware that the competency assessments were not performed, confirming the above findings.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory policy, Quality Control (QC) logs and confirmed in interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure quality laboratory services for high complexity analytical systems. Refer to D6082.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, Quality Control (QC) logs and confirmed in interview, the laboratory director failed to ensure requirements were met for the analytical system, as evidenced by: 1. The laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 2 of 6 days in 2018 (11/2018) and 1 of 4 days in 2019 (07/2019). Refer to D5473, II. This was a repeat deficiency from a recertification survey on 11/07/2017.