

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2188374	(X3) Date Survey Completed 04/18/2024
Name of Provider or Supplier Uderm, Pllc	Street Address, City, State 5243 Little Debbie Pkwy, Ste 111, Ooltewah, TN	
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	During a recertification survey performed on 04.18.2024, the laboratory was found out of compliance with the following condition: 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory's policy, personnel records, and staff interview, the laboratory failed to establish written policies and procedures to assess employee competency and failed to have documentation of initial training, semi-annual, and/or annual competency for one of three high complexity testing personnel. Findings included: 1. A review of the submitted CMS-209 form listed three testing personnel for high complexity testing. 2. A review of the laboratory's policy and procedure manual revealed no written policies or procedures to assess employee competency for testing personnel performing high complexity testing. 3. A review of laboratory personnel records revealed no documented initial training, semi-annual competency, and annual competency assessment for high complexity testing personnel two of three as listed on the CMS-209 4. An interview on 04.18.2024 at 10:25 a.m. with the lead histotechnician confirmed the above survey findings.</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 observation of the laboratory, review of the operator's manuals, environmental records, and staff interview, the laboratory failed to monitor ambient humidity in the area where patient tissue processing occurred in 2022, 2023, and 2024. 1. Observation of the laboratory on 04.18.2024 at 9:10 a.m. revealed two Leica CM 1850 cryostats (serial numbers 35131/05.2003 and 1678/06.2000), one Thermo Scientific Linistat stainer (serial number LS5855A2003), and one Tissue-Tek SCA coverslipper (serial number 47641578) used for processing patient tissue samples removed during MOHS procedures. 2. A review of the operator's manuals revealed the following: -Leica CM 1850 cryostat: air humidity must not exceed 60%. -Linistat stainer: maximum relative humidity 80%. -Tissue-Tek SCA coverslipper: ambient operating humidity range is 30% to 70% relative humidity. 3. A review of the laboratory maintenance logs revealed no humidity records were available for the area where the laboratory processed tissues using the Leica CM 1850 cryostats, Thermo Scientific Linistat stainer, and Tissue-Tek SCA coverslipper in 2022, 2023, or 2024. 4. An interview with the lead histotechnician on 04.18.2024 at 9:24 a.m. confirmed the laboratory did not monitor humidity in the area where patient tissue processing occurred in 2022, 2023, and 2024.

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:

Based on a review of the laboratory's Hematoxylin and Eosin (H&E) stain control slide log, laboratory procedure, and staff interview, the laboratory failed to define the predicted characteristics of the H&E stain in 2022 through the survey date of 04.18.2024. The findings include: 1. A review of the laboratory's H&E stain control slide logs, revealed no documentation of the predicted characteristics of the H&E stain quality for 2022 through the survey date of 04.18.2024. 2. A review of the laboratory's "PROCEDURE FOR STAINING" procedure revealed that it did not define predictable characteristics of the H&E stain quality. 3. During an interview on 04.18.2024 at 12:45 p.m., the Laboratory Director confirmed that they had not defined and/or documented the predicted characteristics of the H&E stain quality for the period between 2022 and the survey date of 04.18.2024.

D5475

CONTROL PROCEDURES

CFR(s): 493.1256(e)(3)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient test records, lack of documentation, and staff interview, the laboratory failed to document the results of positive and negative controls for the Mart-1 immunohistochemical (IHC) stain for four of four micrographically oriented histographic surgery (Mohs) cases reviewed and failed to provide records of the Mart-1 reagent lot numbers and expiration dates for 2022, 2023, and 2024. The findings include: 1. Observation of the laboratory facility on 04.18.2024 at 10:50 a.m. revealed Mart-1 IHC reagents used to stain tissue removed during Mohs surgical procedures. 2. A review of patient test records revealed the use of Mart-1 IHC stain on 09.08.2022 for patient medical record number (MRN) 5352, 04.04.2023 for patient MRN 7917, 11.28.2023 for patient MRN 10124, and 04.04.2024 for patient MRN 52453. None of the selected cases for review had documented results of the positive and negative controls. 3. No documentation was available for surveyor review for historic reagent lot numbers and expiration dates for the reagents used in the Mart-1 IHC stain. 4. An interview with the lead histotechnician on 04.18.2024 at 11:40 a.m. confirmed the laboratory failed to document the results of the positive and negative controls for the Mart-1 stain in 2022, 2023 and 2024 and failed to retain records of lot numbers and expiration dates of the reagents used for performing the Mart-1 stain.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel competency assessments, and interview with the lead histotechnician, the technical consultant failed to evaluate annual competency for one of one moderately complex testing personnel performing Potassium Hydroxide (KOH) patient testing in 2023. The findings include: 1. A review of CMS-209 revealed one testing personnel for moderately complex testing. 2. A review of the laboratory's testing personnel competency assessments revealed no documentation of 2023 annual competency for moderately complex testing personnel, one of one as listed on the CMS-209. 3. An interview with the lead histotechnician on 04.18.2024 at 10:25 a.m. confirmed the above survey findings.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on observation of the laboratory, staff interviews and review of personnel records, laboratory testing personnel performing high complexity inking of tissue removed during micrographically oriented histographic surgery (Mohs) procedure failed to meet the regulatory education requirements (Refer to D6171).

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1,

1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services (CMS) 209 form, interview with the lead histotechnician and laboratory director, review of personnel records, and subsequent interview with the laboratory director, two of three testing personnel performing high complexity testing failed to meet the regulatory education requirements. The findings include: 1. Observation of the laboratory on 04.18.2024 at 9:20 a.m. revealed reagents, stains, and inks used for performing histopathology procedures on tissues obtained by the micrographically oriented histographic surgery (Mohs) procedure. 2. A review of the CMS-209 revealed three testing personnel who perform high complexity patient testing. 3. An interview with the lead histotechnician and laboratory director on 04.18.2024 at 10:20 a.m. revealed that the Mohs surgeon brings tissue to the laboratory, and the histotechnicians (high complexity testing personnel two and three as listed on the CMS-209) ink the tissue. 4. A review of testing personnel records revealed that high complexity testing personnel two and three, as listed on the CMS-209, did not have the required education to perform high-complexity testing. 5. An interview with the laboratory director on 04.18.2024 at 12:45 p.m. confirmed that the histotechnicians inking tissues removed during the Mohs surgical procedure did not meet the regulatory education requirement to perform high-complexity testing.