

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2057929	(X3) Date Survey Completed 11/02/2022
Name of Provider or Supplier Forefront Dermatology S C	Street Address, City, State 395 Northside Dr, Batesville, IN	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label 12 of 12 containers in the Thermo Scientific Linstain (Linstat) to identify reagents used in staining for MOHS micrographic surgery (MOHS) slides for six out of six patients (PT#1-PT#6) reviewed. Findings Included: 1.) During a tour of the MOHS laboratory on 10/26/2022 at 9:57 a.m., revealed a Linstain (Linstat) with 12 different reagents in containers with no labeling to identify the reagents and no posted labeling to identify the sequencing on staining in the stain line. 2.) Review of "Stain Rotation Log" revealed there was no labeling of containers from the Linstain in the log to identify the reagents that were changed. 3.) Review of patient records revealed the following patients had MOHS testing performed: a) PT#1 tested on 2/8/2022 b) PT#2 tested on 4/1/2021 c) PT#3 tested on 11/6/2021 d) PT#4 tested on 12/7/2022 e) PT#5 tested on 6/21/2022 f) PT#6 tested on 10/18/2022 4.) The annual testing volume for MOHS is 742. 5.) During an interview on 10/26/2022 at 2:37 p.m., SP#1 (Office Manager) confirmed the laboratory failed to label the Linstain to identify the 12 reagents in containers.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

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 observation, record review and interview, the laboratory failed to perform maintenance on two of two cryostat (QS12 UV and QS12) and one of one Linstain (Linistat) that were in use for six of 31 days (January 3, 4, 5, 10, 24, and 31) in 2022 when Mohs testing was performed for 39 patients. Findings Included: 1.) 1. During a tour of the MOHS laboratory on 10/26/2022 at 9:52 a.m., revealed the following: a) two cryostats (QS12 UV and QS12) in use for MOHS testing. b) one Linstain (Linistat) in use for stain line in MOHS testing. 2.) Review of the "Instruction Manual The Avantik QS12 and QS12UV Cryostats", on page 47 stated, "daily defrosting is necessary." 3.) Review of "Thermo Scientific Linistat Operator Guide" on page 30 stated "Clean the inner surfaces and compartments as required ... Clean the Staining Jars as required." 4.) Review of the "Policy & Procedure Subject: Laboratory Daily Maintenance MOHS" stated "4. The defrost cycle will be set for routine defrosting. 5. Staining set-up will be changed as needed following the standard operating procedure." 5.) Review of the "Policy & Procedure Subject: Stain Maintenance Auto-Stainer", signed by the laboratory director on 01/2019, stated "1. Staining dishes will be changed as needed, depending on the number of cases and slides ran daily... 3. A QC worksheet is documented daily on the stain quality and any corrections or changes made." 6.) Review of "MOHS Specimen Testing log" revealed 39 patients had MOHS testing performed on the following days: a) January 3, 2022 had eight patients tested. b) January 4, 2022 had five patients tested. c) January 5, 2022 had eight patients tested. d) January 10, 2022 had 8 patients tested. e) January 24, 2022 had 5 patients tested. f) January 31, 2022 had 5 patients tested. 7.) Review of the January 2022 "QS12 Cryostat Maintenance & Temperature Log", signed by testing personnel on 1/31/2022, revealed the following: a. On 1/3/2022 cryostat comment stated "not used". Temperature and maintenance were not filled out. b. On 1/4/2022 cryostat comment stated "not used". Temperature and maintenance were not filled out. c. On 1/5/2022 Temperature and maintenance were not filled out. d. On 1/10/2022 Temperature and maintenance e were not filled out. e. On 1/24/2022 Temperature and maintenance were not filled out. f. On 1/31/2022 cryostat comment stated "not used". Temperature and maintenance were not filled out. 9. Review of January 2022 "Stain Rotation Log" revealed a blank log with no written documentation of maintenance for the Linstain for the entire month in January in 2022. 10.) The annual testing volume for MOHS is 742. 11.) During an interview on 10/26/2022 at 2:37p.m., SP#1 (Office Manager) confirmed the laboratory failed to perform maintenance for the cryostat and Linstain that were in use for six of 31 days (January 3, 4, 5, 10, 24, and 31) in 2022.

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 record review and interview, the laboratory failed to ensure four of five (SP#1, SP#3, SP#4, and SP#5) testing personnel were qualified to perform high complexity testing (grossing) for MOHS. (Refer to 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 record review and interview, the laboratory failed to ensure four of five (SP#1, SP#3, SP#4, and SP#5) testing personnel were qualified to perform high complexity testing (grossing) for MOHS.. Finding included: 1.) Review of the CMS 209 revealed employees SP#1, SP#3, SP#4, and SP#5 were Testing personnel. 2.) Review of the "Policy & Procedure Subject: Training for MOHS Tech", signed by laboratory director in 2022, stated "New histotechs will be trained by an experienced, trained histotech under the direct supervision of Forefront Dermatology Mohs surgeon... Histotechs in training will be educated and evaluated for the following process by their surgeon: a) appropriate grossing and fixation: Specimens are described and trimmed to proper size and preserved in appropriate solutions to prevent composition...d) The Mohs Tech will stain specimens with various chemicals and dyes to assist with the identification of specific tumor cell lines (immunochemistry) to show presence of bacterial and viral infections." 3.) Review of personnel degree records revealed the following: a. SP#1 had a high school diploma and Associate of Applied Science in Medical Assisting. b. SP#3 had a Diploma in Medical Assisting. c. SP#4 had no diploma on file d. SP#5 had no diploma on file 4.) Review of Employee Evaluation revealed the following: a. SP#1 was assessed for proper/orientation technique and dye tissue was signed by laboratory director on 2/28/2022. b. SP#3 was assessed for proper/ orientation technique and dye tissue was signed by laboratory director on 2/28/2022. c. SP#4 was assessed for proper/orientation technique and dye tissue was signed by laboratory director on 2/28/2022. d. SP#5 was assessed for proper /orientation technique and dye tissue was signed by laboratory director signed, but without a date. SP#5 signed on 9/12/22. 5.) Review of "Certificate of Training" revealed SP#1 and SP#3 received training for preparation of frozen sections of Mohs micrographic surgery specimens which included inking and mapping of Mohs skin specimens and special techniques to improve cutting fat and cartilage and minimize folding of lateral epithelial margins. SP#1's certificate was signed by laboratory director on 2/15/15 and SP#3 certificate was signed on 5/15/2020 by the laboratory director. 6.) The annual testing volume for MOHS is 742. 7.) During an interview on 10/26/2022 at 2:37p.m., SP#1 (Office Manager) confirmed the laboratory would send the degrees along with transcripts for all the testing personnel within seven days. On 11/2/2022 Office manager did not send transcripts for the testing personnel.