Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2072762	03/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology, Sc	101 Candlewood Court, Lynchburg, VA	

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 announced CLIA recertification survey was conducted at Forefront Dermatology SC (DBA: Ridgeview Dermatology) on March 24, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows. The laboratory was not in compliance with: D6168 -42 C.F.R. 493. 1487 Condition: Testing Personnel.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: A. Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), procedure manual, proficiency testing (PT) records, and an interview, the laboratory failed to verify Mohs Micrographic examination accuracy twice annually per their policy in the twenty-five (25) months reviewed for Testing Personnel A (TP A). *See Testing Personnel Code Sheet. Findings include: 1. Review of the laboratory's CMS 209 form revealed "TP A" was identified as performing patient Mohs Micrographic Surgery and slide examination /reading during the review timeframe of January 2020 to the date of the inspection on 3/24/22. 2. Review of the procedure manual revealed a written QA policy that outlined twice annual Mohs PT for accuracy documentation. The policy stated: "3 cases Mohs peer review will be verified semi-annually. 3 cases Frozen Section peer review will be verified semi-annually." 3. Review of the available PT records for 2020, 2021, and year to date 2022 revealed 1 record of Mohs peer review (3 cases: 20-006, 20-132, 20-0283 on 12/8/21). The inspector requested additional documentation of Mohs PT for TP A. No additional documentation was available for review. 4. An interview with the clinic manager and lead tech on 3/24/22 at approximately 12:30

	PM confirmed the above findings. B. Based on a review of the CMS 209 personnel form, procedure manual, PT records, and an interview, the laboratory failed to verify twice annual accuracy of Potassium Hydroxide (KOH) and Ectoparasite microscopy examination testing in the twenty-five (25) months reviewed for TP B. *See Testing Personnel Code Sheet. Findings include: 1. Review of the laboratory's CMS 209 form revealed that "TP B" was identified as responsible for performing patient KOH /Ectoparasite microscopy examination testing during the review timeframe of January 2020 to the date of the inspection on 3/24/22. 2. Review of the procedure manual revealed a written quality assurance (QA) policy that outlined twice annual proficiency testing (PT) for accuracy documentation. 3. Review of the available PT records for 2020, 2021, and year to date 2022 revealed one record of KOH /Ectoparasite PT (signed/dated by TP B on 12/21/21). The inspector requested additional documentation of microscopy PT. No additional documentation was available for review. 4. An interview with the clinic manager and lead tech at approximately 12:30 PM confirmed the above findings.
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 a review of equipment maintenance logs, manufacturer's operations manual, lack of documentation, and interviews, the laboratory failed to document performance of required fume hood filter replacement maintenance according to manufacturer's instructions in the twenty-five (25) months reviewed (January 2020 to March 24, 2022). Findings include: 1. Review of the laboratory's equipment maintenance logs revealed no fume hood maintenance in calendar years 2020, 2021 and up to the date of the inspection on 3/24/22. The inspector noted that no filter replacement was documented. Documentation of filter replacement was requested. No records were available. 2. Review of the LabConCo Fume Adsorber Operations Manual revealed instruction statements: "It is important to include filter replacement in routine preventative maintenance schedule. Monthly routine maintenance requires monitoring and/or replacement of carbon filter. Time can be used to anticipate saturation or TWA (recommended Exposure Limits expressed as a Time Weighted Average) levels. However, this does not replace the need for sampling. Consult LabConCo technical specialist for an estimate of carbon filter lifebased on chemical usage. The carbon filters must be checked at intervals of 20% of the total estimated filter life. The exception to the 20% recommendation is formaldehyde and any carcinogen or suspected carcinogen. These more hazardous chemicals must be checked at least every 10% of the total estimated time". 3. The inspector inquired regarding the protocol for changing the fume hood charcoal filter. The lead histotech stated at approximately 11:30 AM: "We have Marston Technical Services provide maintenance for all of our lab equipment. I do not recall that they checked or replaced the filters but I can contact them regarding the LabConCo Fume hood." The inspector requested to review the Marston Technical Services field service maintenance reports for calendar year 2020 and 2021. No records were available for the LabConCo Fume Adsorber hood. 4. An interview with the clinic manager and lead tech at approximately 12:30 PM confirmed the above findings.

D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of procedures, five (5) randomly selected 2021 monthly temperature logs, lack of documentation, and an interview, the laboratory failed to document corrective action on twelve (12) of sixty (60) days reviewed when room temperature/humidity were outside of acceptable limits. Findings include: 1. Review of the laboratory's procedure manual revealed a protocol (title: Lab Thermometer Maintenance revised 7/24/19, reviewed 7/27/21) that outlined: "Check thermometer /humidity daily when lab is in use, reading should be 68-80 degrees Fahrenheit (F) with less than 60 per cent (%) humidity, document on log with initials, if out of range-apply corrective action and notify lab director if necessary". 2. The inspector requested to review temperature logs for the following 5 randomly selected months of calendar year 2021: June, July, August, September, October. The review revealed no corrective action documented when: a. the room temperature was colder than acceptable (less than 68 F) on the following dates: 6/17/21, 7/9/21, 7/21/21, 8/17/21, 8 /20/21, 9/13/21, 9/14/21, 9/16/21, 9/17/21, 9/27/21, 10/12/21; b. the room humidity did not meet protocol criteria (less than 60 %) on the following dates: 9/13/21, 9/14 /21, 10/21/21. 3. The inspector requested to review corrective action for the dates outlined above. No record of corrective action for the above 12 dates when temperature and/or humidity levels were recorded outside of criteria were available. 4. An interview with the clinic manager and lead tech at approximately 12:30 PM confirmed the above 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), a tour, review of testing personnel (TP) training /education records, test logs, procedures, lack of documentation, and interviews, the laboratory failed to ensure that two of three TP met qualifications to perform high complexity grossing procedures of Mohs surgical tissue samples processed from January 2021 through the date of the survey on March 24, 2022. (Cross reference 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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), a laboratory tour, review of testing personnel

	(TP) training/education records, lack of documentation, procedure manual, test logs, and interviews, the laboratory failed to ensure that two (2) of three (3) TP met qualifications to perform high complexity testing while grossing Mohs dermatology surgical tissue samples from January 2021 through the date of the survey on March 24, 2022. Findings include: 1. Review of the laboratory's CMS 209 form revealed 3 TP were identified by the lab director (LD) as responsible for high complexity Mohs laboratory duties (TP C, D, and E). *See Personnel Code Sheet. 2. During a tour of the laboratory on 3/24/22 at approximately 10:00 AM, the inspector observed "TP C" performing grossing/processing procedures of patient Mohs surgical tissue samples. The inspector inquired as to who performs the grossing/inking of specimens. "TP C" stated at approximately 10:15 AM: "I perform grossing here on the grossing mat and also ink". 3. Review of records revealed that the transcripts of "TP C" and "TP D" lacked evidence of the required educational elements to qualify for histopathology high complexity grossing/inking procedures. The inspector noted a Testing Personnel Responsibilities form in each TP's file that stated: "If qualified, the TP must perform high complexity testing only under the onsite direct supervision of a general supervisor". The inspector inquired of the supervision description (outlined above). The clinic manager with the lead tech stated at approximately 12:00 PM that: "The techs were trained during a workshop in January 2021 by Beck Consulting in which they received a certificate of training in Mohs Mircrographic Technology. Their work is not always under direct supervision of the director." The inspector noted initial training for the TP outlined was dated January 2021, semi annual completed July 2021, annual January 2022. 4. Review of the laboratory procedure manual revealed a histotech tissue prep guide: "Receive tissue specimen, fill out log sheet, fill in Moh's number on map, match tissue to Dr's drawing/body chart/nics, decide if tissue will be cut into sections, draw out/cut/label sections, color code sections, cut tissue, color tissue." 5. Review of the laboratory patient logs for the timeframe outlined above revealed: TP C competed 1,194 Mohs cases; TP D completed 29 Mohs cases. 6. An interview with the clinic manager and lead tech at approximately 12:30 PM confirmed the above findings.