Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0675623	09/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Forefront Dermatology Sc	8301 Old Courthouse Rd, Vienna, 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 on September 14, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The specific deficiencies are as follows:
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 policy and procedure manual, "Quality Control Assessment of Mohs Tissue Staining Procedure" log sheet, Mohs Surgery specimen logs, lack of documentation and interviews, the laboratory failed to follow their established policy and document the intended reactivity for Hematoxylin and Eosin (H&E) stain for four (4) days of two-hundred forty-two (242) days of Mohs surgery during the review timeframe of January 1, 2021 until September 14, 2022 while reporting forty-two (42) patients. Findings include: 1. Review of the procedure manual revealed a policy, "Hematoxylin and Eosin Stain-Quality Control", which stated: "The first slide of the day will be submitted to the Mohs surgeon for the completion of the daily quality control and will be performed using a random non-diagnostic tissue specimen. The slide will be stained for H & E and documented on the control sheet. The slide will be labeled as QC and dated, and kept in the file with current cases. This slide will show, blue nuclei and pink cytoplasm." 2. Review of the "Quality Control Assessment of Mohs Tissue Staining Procedure" log sheet and Mohs Surgery specimen log sheets from January 1, 2021 until September 14, 2022 revealed

	a lack of documentation of the intended reactivity for H&E Quality Control (QC) slide for the following dates: 03/25/2021 - 10 patients; 02/02/2022 - 8 patients; 02/24 /2022 - 11 patients; 04/12/2022 - 13 patients. A total of 42 patients. The surveyor requested to review documentation of the intended reactivity for H&E QC slide for the above listed dates. The laboratory was unable to provide documentation of the intended reactivity of the H & E QC slide for the dates listed above. The laboratory was able to provide the H & E QC slides for each of the dates listed above. 3. In an exit interview with the Mohs Technician on September 14, 2022 at approximately 11: 30 AM, the above findings were confirmed.
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 the laboratory's policies and procedures, daily temperature charts, lack of documentation, and interviews, the laboratory failed to follow their established policy and document corrective action on the dates the room temperature of the laboratory was outside of acceptable limits for forty-four (44) days of two-hundred forty-two (242) days of Mohs surgery during the review timeframe of January 1, 2021 until September 14, 2022. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a policy, "Lab Thermometer Maintenance", which stated "1. Check the thermometer/humidity daily when lab is in use. 2. It should read 68 to 80 F Temperature with Less than 60% Humidity. 3. Document that thermometer check has been completed by initialing log-722-B Room Temp/Humidity Chart. 4. If out of range, apply correction as necessary and notify lab director." 2. Review of log-722-B "Room Temperature/Humidity" chart from January 1, 2021 to the date of the survey on September 14, 2022 revealed a lack of corrective action documentation when the Room Temperature was warmer than acceptable (greater than 80 degrees Fahrenheit) on the following dates: 02/24/2021, 02/25/2021, 03/04/2021, 03/08/2021, 03/10/2021, 03/11/2021, 03/24/2021, 03/25/2021, 03/31 /2021, 04/07/2021, 10/20/2021, 10/21/2021, 11/04/2021, 11/08/2021, 11/24/2021, 12 /01/2021, 12/02/2021, 12/06/2021, 12/15/2021, 12/16/2021, 12/20/2021, 12/22/2021, 02/23/2022, 03/02/2022, 03/03/2022, 03/07/2022, 03/10/2022, 03/23/2022, 03/31 /2022, 04/13/2022, 04/14/2022, 04/25/2022, 04/27/2022, 05/04/2022, 05/05/2022, 05 /09/2022, 05/11/2022, 05/16/2022, 05/18/2022, 05/19/2022, 05/23/2022, 05/25/2022, 05/26/2022, and 06/01/2022. The inspector requested to review corrective actions taken for the dates listed above when the temperatures were outside the laboratory's established criteria. The laboratory provided no documentation of corrective actions taken for review. 3. In an exit interview with the Mohs Technician on September 14, 2022 at approximately 11:30 AM, the above findings were confirmed.